IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION, Plaintiff, v. LIQUIDIA TECHNOLOGIES, INC., Defendant.	)	**Redacted - Public Version** C.A. No. 23-975-RGA-SRF

DECLARATION OF DOUGLAS KIDDER

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1. SCOPE OF WORK

1. I have been retained on behalf of Defendant Liquidia Technologies, Inc. ("Liquidia") to review and comment on the declaration submitted by Frederic Selck dated February 26, 2024 (the "Selck Declaration") on behalf of Plaintiff United Therapeutics Corporation ("UTC" or "UTHR"). I understand that UTC alleges that Liquidia infringes certain claims of UTC's U.S. Patent No. 11,826,327 (the "'327 Patent").[1]

2. In forming my opinions as expressed in this declaration, I have assumed that the '327 Patent is valid, enforceable, and infringed. The opinions contained in my report are based on the information and data available to me as of the date of serving this report. If new data or information becomes available, I expect to update or revise my opinions accordingly.

2. QUALIFICATIONS

3. My name is Douglas Kidder. I am a Managing Partner with OSKR, LLC, a firm that provides expert services primarily in the area of damages calculations generally with a particular focus on intellectual property and antitrust matters. I was also an adjunct professor at Golden Gate University, where I taught a graduate course on damages in the school of accounting. I am also a member of the Licensing Executives Society, a former Director of i-cap Partners – a venture capital fund investing in technology companies – and a former member of the Trade New Zealand advisory board – a group formed to review New Zealand-based startups for support entering the U.S. market.

4. I hold a B.A. in Mathematics and English with Honors from Amherst College (1983) and a Master of Science from the University of California at Berkeley (1986). While at Berkeley, I was a lecturer in the Computer Science department.

5. I have been performing business analyses and valuations for over thirty-five years, as a consultant, business owner, board member and manager. I have been retained by companies to render expert opinions in the context of litigation, to assist in licensing and evaluation of intellectual property that is not subject to litigation, and to develop and refine business strategies. I have published and spoken on business and valuation issues, mostly related to intellectual property. I have co-authored seven published articles relating to intellectual property damages. A copy of my resume is attached as Exhibit 1. A list of the documents considered in forming my opinions is attached as Exhibit 2.

[1] First Amended Complaint for Patent Infringement, United Therapeutics Corporation. v. Liquidia Technologies, Inc., Case No. 1:23-cv-00975, Nov. 30, 2023 (hereafter the "Complaint").

6. I am being compensated at an hourly rate of $750 per hour, plus reimbursement of expenses. I have been assisted in this matter by OSKR staff, working under my supervision and control. I have no financial interest in the outcome of this matter.

3. SUMMARY OF OPINIONS

7. Dr. Selck's opinions lack merit and are contradicted by evidence from UTC. Dr. Selck's opinions about price erosion and lost sales are directly refuted by UTC management's statements and internal forecasts. For example, UTC's Chairman and CEO, Martine Rothblatt stated publicly that:

> I think our double-digit growth rate remains a solid forecast even with the possibility of new FDA approvals of sotatercept or Liquidia. [2]

A review of the evidence supports Dr. Rothblatt's statements. UTC's internal financial forecast [redacted].

8. Despite this evidence, Dr. Selck opines that the launch of Yutrepia – with or without a PH-ILD indication – will result in price erosion and lost sales for Tyvaso.[3] Further, Dr. Selck has not supported a nexus between his opinions on price erosion and lost sales and the launch of Yutrepia with a PH-ILD indication. His only support for his opinion that UTC will suffer additional harm if Yutrepia launches with a PH-ILD indication is a single, undocumented conversation with a UTC employee. [4] Thus, there is not even a reasonable supposition of harm from Yutrepia's launch, much less harm from Yutrepia's launch with a PH-ILD indication.

9. Furthermore, any such harm would apparently happen slowly, if at all. In Dr. Selck's analysis, the harm to UTC would occur in his proposed "PH-ILD Market" – a market that he describes as "nascent" with a "rate-limiting step."[5] I note that Dr. Selck characterizes the proposed market as "nascent" three

[2] LIQ_PH-ILD_00001135-1145 at 1137 [Refinitiv Edited Transcript UTHR.0Q - Q1 2023 United Therapeutics Corp Earnings Call, May 3, 2023]

[3] Deposition of Frederic Selck, March 15, 2024 at 41:14–42:21, 62:6–16.

[4] Selck Declaration, ¶10. Deposition of Frederic Selck, March 15, 2024 at 28:21 – 29:3. [redacted]

[5] Selck Declaration, ¶17; Deposition of Frederic Selck, March 15, 2024 at 131:18–132:8.

years after Tyvaso was first approved for a PH-ILD indication.[6] A market that is still "nascent" after three years with a "rate-limiting step" suggests a lack of urgency even if the patent is assumed to be found valid and infringed at a trial in 2025.

10. Dr. Selck's additional opinions regarding indirect harms such as loss of first mover advantage, reputational harm, irreparability and the balance of equities fail because they all derive from his flawed opinions regarding lost sales and price erosion. There is no evidence in this case that any harm would be irreparable: damages will be calculable using standard patent damages methodologies and there is nothing to suggest that the quantum of damages will be so great that Liquidia will be unable to pay them. The balance of equities favors Liquidia. UTC has over $4.9 billion in cash and a business that is generating an additional $700 million in cash each year.[7]

4. BACKGROUND

11. In the following sections I provide an overview of UTC, Liquidia and the dispute. The sections describing UTC and Liquidia also offer background into PAH, PH-ILD and therapies for treating these conditions.

4.1 UTC

12. UTC describes itself as a public benefit corporation that sells a range of therapies:

> We are the first publicly-traded biotech or pharmaceutical company to take the form of a public benefit corporation (PBC). Our public benefit purpose is to provide a brighter future for patients through (a) the development of novel pharmaceutical therapies; and (b) technologies that expand the availability of transplantable organs. At the same time, we seek to provide our shareholders with superior financial performance and our communities with earth-sensitive energy utilization.
>
> We market and sell the following commercial therapies in the United States to treat PAH: Tyvaso DPI® (treprostinil) Inhalation Powder (Tyvaso DPI); Tyvaso® (treprostinil) Inhalation Solution (nebulized Tyvaso), which includes the Tyvaso Inhalation System; Remodulin® (treprostinil) Injection (Remodulin); Orenitram® (treprostinil) Extended-Release Tablets (Orenitram); and Adcirca® (tadalafil) Tablets (Adcirca). Tyvaso DPI and nebulized Tyvaso are also approved to treat pulmonary hypertension associated with interstitial lung disease (PH-ILD). In the United States, we market and sell an oncology product, Unituxin® (dinutuximab) Injection (Unituxin), which is approved for the treatment of high-risk neuroblastoma, and the Remunity® Pump for

[6] *See* FDA, Tyvaso (treprostinil) Approval Letter, 3/31/2021 (LIQ_PH-ILD_00001433), available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/022387Orig1s017.pdf.

[7] United Therapeutics Corporation Form 10-K for the year ending December 31, 2023 ("UTC 10-K, 2023"), p. 61.

> Remodulin (Remunity). Outside the United States, we derive revenues from sales of nebulized Tyvaso, Remodulin, and Unituxin.
>
> We are actively advancing a pipeline of research and development projects that includes new indications and delivery devices for our existing products, as well as new products to treat PAH and other conditions. We are also focused on a variety of manufactured organ products with the goal of addressing the chronic shortage of transplantable organs for patients with end-stage organ diseases.[8]

13. In 2023 the majority of UTC's sales came from different formulations of Treprostinil with approximately half of its revenues came from sales of Tyvaso in the U.S.:

	2023		
	U.S.	ROW	Total
Net product sales:			
Tyvaso DPI[(1)]	$ 731.1	$ –	$ 731.1
Nebulized Tyvaso[(1)]	477.1	25.5	502.6
Total Tyvaso	1,208.2	25.5	1,233.7
Remodulin[(2)]	414.6	80.2	494.8
Orenitram	359.4	–	359.4
Unituxin	181.3	17.6	198.9
Adcirca	28.9	–	28.9
Other	9.8	2.0	11.8
Total revenues	$2,202.2	$ 125.3	$2,327.5

Table 1: UTC Revenues by Product[9]

14. UTC describes competition for its products as:

> Many drug companies engage in research, development, and commercialization of products to treat cardiopulmonary diseases and cancer. For the treatment of PAH, we compete with many approved products in the United States and the rest of the world. In the U.S., these competitive therapies include oral ERAs (Letairis® (ambrisentan), Opsumit® (macitentan), Tracleer® (bosentan), generic bosentan, and generic ambrisentan); prostacyclin-class therapies (Flolan (intravenous epoprostenol), Uptravi® (oral selexipag), Veletri® (intravenous epoprostenol), Ventavis® (inhaled epoprostenol), generic epoprostenol, and generic treprostinil injection); PDE-5 inhibitors (Revatio® (sildenafil), generic sildenafil, and generic tadalafil); and Adempas® (riociguat), an sGC stimulator that targets a similar vasodilatory pathway as PDE-5 inhibitors. These therapies are manufactured and marketed by large pharmaceutical companies such as Johnson & Johnson, Gilead Sciences, Inc., and Bayer Schering Pharma AG, as well as a variety of large generic drug manufacturers.

[8] UTC 10-K, 2023, p. 3.

[9] UTC 10-K, 2023, p. F-33.

There are also a wide variety of investigational PAH therapies in development. Therapies in registration-phase studies, or which have completed registration-phase studies, include the following:

- Yutrepia a dry powder formulation of treprostinil developed by Liquidia, which is designed for pulmonary delivery using a disposable inhaler. In November 2021, Liquidia announced the FDA granted tentative approval for its NDA for Yutrepia to treat PAH, with final approval pending resolution of the regulatory stay triggered by the litigation described above under Patent and Other Property Rights, Strategic Licenses, and Market Exclusivity—Generic Competition and Challenges to our Intellectual Property Rights. In late 2020, Liquidia completed a business combination with RareGen, LLC, which markets a generic version of Remodulin manufactured by Sandoz. Liquidia has submitted an amendment to the Yutrepia NDA to include a PH-ILD indication. In September 2023, Liquidia announced that the FDA had accepted this amendment for review, and set a PDUFA target action date of January 24, 2024. On January 25, 2024, Liquidia announced that the FDA had not yet completed its review of the NDA and did not provide an updated timeline. The regulatory process concerning Liquidia's NDA is subject to the litigation described in Note 14—Litigation, to our consolidated financial statements.
- Sotatercept, an injected activin signaling inhibitor being developed by Acceleron Pharma, Inc. (Acceleron), which was acquired by Merck, to treat PAH thorough the TGF-beta signaling pathway. Merck announced positive top-line results of a phase 3, registration trial in PAH called STELLAR in October 2022, and submitted an NDA to the FDA with a PDUFA target action date of March 26, 2024. Acceleron indicated it may also study sotatercept in PH-ILD patients.
- Imatinib, a drug currently used to treat cancer under the trade name Gleevec®, is being developed separately for the treatment of PAH by three companies. Tenax Therapeutics, Inc. announced plans to initiate a phase 3 study of an oral formulation. Aerovate Therapeutics, Inc. is conducting a phase 2/3 clinical study of an inhaled, dry powder formulation of imatinib. Aerami Therapeutics Holdings, Inc. completed a phase 1 trial of an inhaled formulation of imatinib in 2023, and has announced plans for a phase 2 study in PAH and PH-ILD patients.
- MK-5475, an inhaled soluble guanylate cyclase stimulator being developed by Merck for PAH in a phase 2/3 trial and in a phase 2 trial for PH-COPD patients.
- L606, an inhaled, liposomal form of treprostinil being developed by Pharmosa Biopharm Inc. (Pharmosa) for PAH and PH-ILD, which completed a phase 1 study in healthy volunteers. In June 2023, Liquidia announced it had entered into an exclusive licensing agreement for development and commercialization of L606 in North America, and that the product is the subject of a phase 3 clinical trial in patients with PH-ILD, with the intent of obtaining approval for the treatment of both PAH and PH-ILD via the 505(b)(2) regulatory pathway, with nebulized Tyvaso as the reference listed drug.

> Additional therapies being studied for PAH include Insmed Incorporated's TPIP (INS1009, an inhaled version of treprostinil) (phase 2); Keros Therapeutics' KER-012 (phase 2); Novartis' LTP001 (phase 2); Gossamer Bio, Inc.'s seralutinib (GB002) (phase 3); SoniVie's TIVUS™ (pivotal trial); Respira Therapeutics' vardenafil (RT234) (phase 2b); and Cereno Scientific's valproic acid (CS1) (phase 2).
>
> Oral non-prostacyclin therapies (such as PDE-5 inhibitors and ERAs) are commonly prescribed as first-line treatments for less severely ill PAH patients. As patients progress in their disease severity, additional advanced approved therapies, such as inhaled prostacyclin analogues (including Tyvaso DPI and nebulized Tyvaso) or infused prostacyclin analogues (including Remodulin) are then commonly added. Orenitram was the first approved oral prostacyclin-class therapy for PAH in the United States, and offers a more convenient alternative therapy to Remodulin, Tyvaso DPI, and nebulized Tyvaso. The use of available oral therapies could delay many patients' need for inhaled or infused prostacyclin therapy. As a result, the availability of oral therapies affects demand for our inhaled and infused products. In addition, sotatercept presents a potential new way of treating PAH, and if approved, could provide added competition for our treprostinil-based therapies. A majority of patients enrolled in the STELLAR clinical trials of sotatercept were on background prostacyclin class therapies such as treprostinil. We believe sotatercept may offer a complementary treatment in combination with our treprostinil-based therapies, although some physicians could choose to prescribe sotatercept prior to initiating prostacyclin therapy.
> …
> Tyvaso DPI, nebulized Tyvaso, and our other treprostinil-based products may face competition from Liquidia if it obtains final FDA approval of Yutrepia, a dry powder inhaled version of treprostinil.
>
> Aside from Tyvaso DPI and nebulized Tyvaso, there are currently no approved therapies to treat PH-ILD. Several PAH drug candidates are also being developed for PH-ILD (e.g., Yutrepia, L606, sotatercept, imatinib, and TPIP). Other companies are now developing, or may in the future develop, other therapies to treat PH-ILD. In addition, the use of antifibrotic therapies to treat underlying lung disease (such as the IPF therapies discussed below) could delay the onset of group 3 pulmonary hypertension.[10]

4.2 LIQUIDIA

15. Liquidia describes itself as a "biopharmaceutical company focused on the development, manufacture, and commercialization of products that address unmet patient needs, with current focus directed towards the treatment of pulmonary hypertension ('PH')."[11]

[10] UTC 10-K, 2023, pp. 19–20.

[11] Liquidia Corporation Form 10-K for the year ending December 31, 2022 ("Liquidia 10-K, 2022"), p. 3.

16. Liquidia currently generates revenue from sales of an injectable Treprostinil and is researching applications for its PRINT technology:

> We currently generate revenue pursuant to a Promotion Agreement between Liquidia PAH and Sandoz Inc. ("Sandoz") sharing profit derived from the sale of Sandoz's substitutable generic treprostinil injection ("Treprostinil Injection") in the United States. Liquidia PAH has the exclusive rights to conduct commercial activities to encourage the appropriate use of Treprostinil Injection. We employ a targeted sales force calling on physicians and hospital pharmacies in the treatment of pulmonary arterial hypertension ("PAH"), as well as key stakeholders involved in the distribution and reimbursement of Treprostinil Injection. Strategically, we believe that our commercial presence in the field will enable an efficient base to expand from for the launch of YUTREPIA upon potential approval, leveraging existing relationships and further validating our reputation as a company committed to supporting PAH patients.
>
> We conduct research, development, and manufacturing of novel products by applying our subject matter expertise in cardiopulmonary diseases and our proprietary PRINT® technology, a particle engineering platform that enables precise production of uniform drug particles designed to improve the safety, efficacy, and performance of a wide range of therapies. Through development of our own products and research with third parties, we have experience applying PRINT across multiple routes of administration and drug payloads including inhaled therapies, vaccines, biologics, nucleic acids and ophthalmic implants, among others.
>
> Our lead product candidate is YUTREPIA for the treatment of PAH. YUTREPIA is an inhaled dry powder formulation of treprostinil designed with PRINT to improve the therapeutic profile of treprostinil by enhancing deep lung delivery while using a convenient, low resistance dry-powder inhaler ("DPI") and by achieving higher dose levels than the labelled doses of current inhaled therapies. The United States Food and Drug Administration ("FDA") tentatively approved our New Drug Application ("NDA") for YUTREPIA for the treatment of PAH in November 2021. The FDA also confirmed that the clinical data in the NDA would support our pursuit of a supplemental NDA to treat patients with pulmonary hypertension and interstitial lung disease (PH-ILD) upon the expiration of regulatory exclusivity for the nebulized form of treprostinil in March 2024. [12]

17. Liquidia describes the patient population with PAH and PH-ILD and available therapies as:

> PAH is a rare, chronic, progressive disease caused by hardening and narrowing of the pulmonary arteries that can lead to right heart failure and eventually death, with an estimated diagnosed, treated prevalence in the United States of approximately 30,000 to 45,000 patients. There is currently no cure for PAH, so the goals of existing treatments are to alleviate symptoms, maintain or improve functional class, delay disease progression and improve quality of life.

[12] Liquidia 10-K, 2022, p. 3.

> PH-ILD is the second most prevalent form of Group 3 PH (precapillary PH due to lung disease). ILD is a diverse collection of up to 150 different pulmonary diseases, including interstitial pulmonary fibrosis (IPF), chronic hypersensitivity pneumonitis, connective tissue disease related ILD, and sarcoidosis among others. Current estimates of diagnosed and undiagnosed prevalence of PH-ILD range between 30,000 to 70,000, depending on the growth on the underlying lung diseases. The prevalence of PH in many of these underlying ILD diseases is not yet known due to factors including underdiagnosis and lack of approved treatments until recently.
> …
> The only inhaled prostacyclin analogs approved by the FDA are nebulized Ventavis® (iloprost), nebulized Tyvaso® (treprostinil), and Tyvaso DPI® (treprostinil), a dry powder inhaled formulation. With regard to PH-ILD, there is growing medical preference for inhaled therapies to avoid ventilation-perfusion mismatch resulting from systemic delivery of prostacyclins. In March 2021, the FDA approved Tyvaso® as the only treatment for PH-ILD, later adding Tyvaso DPI as a treatment option upon its approval by the FDA in May 2022.[13]

18. Liquidia believes that Yutrepia offers advantages relative to other therapies for PAH and PH-ILD:

> We believe YUTREPIA can become the prostacyclin of first choice across the disease continuum in PAH and PH-ILD because of its convenience, low-resistance device and the ability to titrate to higher doses.
> …
> In clinical studies required for approval, YUTREPIA has proven to be safe, well-tolerated and effective regardless of a patient's previous exposure to treprostinil. Prostacyclin-naïve patients achieved comparable dosing to the transition patients within first two months of treatment. Patients on a stable dose of Tyvaso successfully transition to YUTREPIA while maintaining or improving clinical outcomes as measured by exploratory endpoints. The combination of data form both patient groups provide confidence that a physician may prescribe YUTRPEIA across a continuum of PAH and PH-ILD patients.[14]

19. Liquidia identified the following competition for Yutrepia:

- Tyvaso …
- Ventavis …
- Tyvaso DPI …
- Treprostinil Palmitil Inhalation Powder (TPIP), is a dry-powder formulation of a treprostinil prodrug being developed by Insmed. Insmed announced the completion of an initial Phase 1 study in February 2021 which demonstrated that TPIP was generally safe and well tolerated, with a pharmacokinetic profile that supports once-daily dosing. Insmed initiated Phase 2 trials studying patients diagnosed with PAH and PH-ILD in May 2021 and December 2022, respectively. If

[13] Liquidia 10-K, 2022, pp. 3–4.

[14] Liquidia 10-K, 2022, p. 5.

> the TPIP clinical program is successful in demonstrating less frequent dosing with similar efficacy and safety to YUTREPIA and Tyvaso DPI, then TPIP has the potential to be viewed as a more attractive option and may take market share rapidly.
> - L606 …
>
> There are also a variety of investigational PAH therapies in the later stages of development that target new or clinically-validated mechanism of actions (MOAs) that may benefit patients. The approval of some or any of these could change the treatment paradigm and impact the utilization of treprostinil products and the prostacyclin pathway at large. We believe that new MOAs may slow or reverse the disease progression of PAH having the net impact of increasing the diagnosed prevalent population by extending patient lives and increasing the potential addressable population for treprostinil-based therapies. For example, Merck & Co's injectable sotatercept is an investigational, potential first-in-class molecule that targets the proliferation of cells in the pulmonary vasculature and is being reviewed by the FDA for approval in 2023. If approved, we currently expect that the drug will be used as it was studied: on-top of dual and triple background therapy that included prostacyclin analogs.[15]

20. In 2023, Liquidia generated $17.5 million in revenue and losses of $78.5 million:

[15] Liquidia 10-K, 2022, p. 14.

Table 2: Liquidia Income Statement[16]

	Year Ended December 31,	
	2023	2022
Revenue	$ 17,488	$ 15,935
Costs and expenses:		
Cost of revenue	2,888	2,859
Research and development	43,242	19,435
General and administrative	44,742	32,411
Total costs and expenses	90,872	54,705
Loss from operations	(73,384)	(38,770)
Other income (expense):		
Interest income	3,466	1,090
Interest expense	(6,273)	(2,338)
Loss on extinguishment of debt	(2,311)	(997)
Total other expense, net	(5,118)	(2,245)
Net loss and comprehensive loss	$ (78,502)	$ (41,015)

4.3 '327 PATENT

21. U.S. Patent 11,826,327 was applied for on April 16, 2021, and granted on November 28, 2023.[17] The title and abstract of the patent read:

> **Treatment for interstitial lung disease**
> Methods of treating of interstitial lung disease, reducing pulmonary function decline in a subject with interstitial lung disease (ILD), and increasing forced vital capacity (FVC) in a subject suffering from ILD are provided, wherein the methods include administration of treprostinil. [18]

22. The '327 Patent contains a single independent claim and 18 dependent claims. Claim 1 reads:

> A method of improving exercise capacity in a patient having pulmonary hypertension associated with interstitial lung disease, comprising administering by inhalation to the patient having pulmonary hypertension associated with interstitial lung disease an effective amount of at least 15 micrograms up to a maximum tolerated dose of treprostinil or a pharmaceutically acceptable salt thereof in a single administration event that comprises at least 6 micrograms per breath. [19]

[16] Liquidia Corporation Form 10-K for the year ending December 31, 2023 ("Liquidia 10-K, 2023"), p. 81.

[17] U.S. Patent 11,826,327.

[18] U.S. Patent 11,826,327.

[19] U.S. Patent 11,826,327.

23. I understand that, for the purposes of its motion for preliminary injunction, UTC asserts that Liquidia induces infringement of claims 1, 6, 9–11 and 14 of the '327 Patent.[20]

4.4 INJUNCTION REQUEST

24. It is my understanding that Liquidia is currently preparing to sell its inhaled dry powder formulation of Treprostinil, Yutrepia, in the United States when permitted by the U.S. Food and Drug Administration ("FDA") after April 1, 2024.[21] I further understand that Yutrepia has been tentatively approved by the FDA for Pulmonary Arterial Hypertension ("PAH") indication. I also understand that an amendment of the New Drug Application (NDA) for Yutrepia for the Pulmonary Hypertension – Interstitial Lung Disease ("PH-ILD") indication is currently pending before the FDA.[22]

25. UTC is requesting a preliminary injunction to prevent Liquidia from launching with the PH-ILD indication:

> Defendant Liquidia Technologies, Inc. ("Liquidia") … shall not engage in the commercial manufacturing, marketing, storing, importing, distributing, offering for sale, and/or selling in the United States of Yutrepia, … for the treatment of pulmonary hypertension associated with interstitial lung disease …[23]

26. Because the requested injunction in this case will not impact Liquidia's launch of Yutrepia for at least the PAH indication, the relevant question is how much additional impact, if any, will the sale and marketing of Yutrepia with both the PH-ILD and PAH indications have versus the sale and marketing of Yutrepia with only the PAH indication.

4.5 TIMELINE OF EVENTS

27. The following chart provides a timeline showing key dates for UTC and Liquidia.

Table 3: Timeline of Events

UTC	Liquidia
2002: Remodulin received FDA approval for subcutaneous administration and began being sold commercially[24]	

[20] Plaintiff's Brief in Support of its Motion for Preliminary Injunction, February 26, 2024, p. 5.

[21] Liquidia 10-K, 2023, pp. 4–5.

[22] 7.24.23 Liquidia Notice Letter to UTC.pdf.

[23] Plaintiff's Motion for Preliminary Injunction, February 26, 2024.

[24] UTC 10-K, 2023, p. 5

2004: Remodulin approved for intravenous administration.[25]	
July 2009: Tyvaso (nebulized) received FDA approval for PAH.[26]	
2013: Orenitram received FDA approval.[27]	
	July 26, 2018: Liquidia started trading on NASDAQ[28]
	January 2020: Liquidia submitted NDA to FDA for Yutrepia approval.[29]
June 2020: Suit filed against Yutrepia in late 2021 for infringement of '901 and '066 Patents ('901 dropped Dec '21 after claim construction).[30] July 2020: '793 Patent added to suit. [31]	
December 2020: Study completed, which "demonstrated the safety and tolerability of Tyvaso DPI in subjects with PAH transitioning from Tyvaso Inhalation Solution, and comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution."[32]	
January 2021: Study announced (completed October 2020) showing "comparable systemic treprostinil exposure between Tyvaso DPI and Tyvaso Inhalation Solution."[33] March 31, 2021: Tyvaso (nebulized) received FDA approval for PH-ILD.[34] UTC announced	

[25] UTC 10-K, 2023, p. 5

[26] UTC 10-K, 2023, p. 4; United Therapeutics Announces FDA Approval and Launch of Tyvaso® for the Treatment of Pulmonary Hypertension Associated with Interstitial Lung Disease, PR NEWSWIRE (4/1/2021), available at https://www.prnewswire.com/news-releases/united-therapeutics-announces-fda-approval-and-launch-of-tyvaso-for-the-treatment-of-pulmonary-hypertension-associated-with-interstitial-lung-disease-301260212.html.

[27] UTC 10-K, 2023, p. 6

[28] https://www.liquidia.com/news-releases/news-release-details/liquidia-technologies-announces-pricing-initial-public-offering

[29] UTC 10-K, 2023, p. 15.

[30] Liquidia 10-K, 2022, p. 65.

[31] Liquidia 10-K, 2022, p. 65.

[32] United Therapeutics Corporation Form 10-K for the year ended December 31, 2022 ("UTC 10-K, 2022"), p. 5.

[33] UTC 10-K, 2022, p. 5.

[34] https://www.accessdata.fda.gov/drugsatfda_docs/nda/2021/022387Orig1s017.pdf

the approval the following day (April 1, 2021).[35] April 16, 2021: '327 Patent filed.[36]	November 5, 2021: Yutrepia received tentative FDA approval for PAH.[37]
August 2021: IPR Proceedings related to '793 Patent began.[38]	
May 23, 2022: Tyvaso DPI received FDA approval for both PAH and PH-ILD.[39] UTC announced approval following day (May 24, 2022).[40] June 2022: Tyvaso DPI launched commercially.[41]	
July 19, 2022: IPR proceedings on the '793 Patent found all claims unpatentable. [42]	
August 31, 2022: District court found Liquidia's product would infringe '793 Patent. ('066 found partially invalid and partially not infringed) [43]	
July 2023: Appellate court affirmed district court ruling on '793 Patent.[44]	
September 5, 2023: New suit filed on '793 Patent related to PH-ILD indication[45]	
November 28, 2023: '327 Patent issued.[46]	

[35] Press Release, United Therapeutics Corp., United Therapeutics Announces FDA Approval and Launch of Tyvaso® For The Treatment Of Pulmonary Hypertension Associated With Interstitial Lung Disease (4/1/2021) (LIQ_PH-ILD_00000952), available at https://pipeline.unither.com/wp-content/uploads/2021/05/2021-04-01-INCREASE-approval-FINAL-formatted.pdf

[36] U.S. Patent 11,826,327.

[37] Liquidia Website, Pipeline (LIQ_PH-ILD_00002443), https://www.liquidia.com/products-and-pipeline/overview (accessed 4/1/2024.)

[38] UTC 10-K, 2023, p. 16.

[39] FDA, NDA 214324 Approval Letter (5/23/2022), available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/214324Orig1s000ltr.pdf

[40] Press Release, United Therapeutics Corp., United Therapeutics Announces FDA Approval Of Tyvaso DPI™ (5/24/2022) (LIQ_PH-ILD_00000988), available at https://ir.unither.com/~/media/Files/U/United-Therapeutics-IR/documents/press-releases/2022/2022-05-24-DPI-approval-FINAL-formatted.pdf

[41] UTC 10-K, 2023, p. 4

[42] UTC 10-K, 2023, p. 16; *United Therapeutics Corp. v. Liquidia Techs., Inc*., 74 F.4th 1360, 1364 (Fed. Cir. 2023), available at https://cafc.uscourts.gov/opinions-orders/22-2217.OPINION.7-24-2023_2161663.pdf, p. 4.

[43] UTC 10-K, 2023, p. 15; *Liquidia Techs., Inc. v. United Therapeutics Corp.*, No. 23-804, 2024 WL 305626, at *9 (U.S. Jan. 23, 2024) (LIQ_PH-ILD_00001172), available at https://www.supremecourt.gov/DocketPDF/23/23-804/298456/20240123132035555_23-____PetitionForAWritOfCertoriari.pdf.

[44] UTC 10-K, 2023, p. 15.

[45] UTC 10-K, 2023, p. 16.

[46] U.S. Patent 11,826,327.

November 30, 2023: Amended complaint added '327 patent. [47]
December 20, 2023: Federal Circuit affirmed IPR decision to invalidate claims of '793 Patent.[48]
January 22, 2024: '793 Patent from withdrawn from suit. [49]
February 20, 2024: UTC filed lawsuit against FDA. [50]
March 12, 2024: Federal Circuit declined UTC's request to rehear decision affirming IPR decision invalidating claims of '793 Patent.[51]
March 2024: UTC FDA clinical trial exclusivity for PH-ILD set to expire[52]
March 28, 2024: District Court vacates judgment of infringement on the '793 patent and vacates order blocking final approval of Liquidia's NDA.[53]

5. OVERVIEW OF THE SELCK DECLARATION

28. Dr. Selck offers opinions regarding the harms he believes UTC will suffer absent an injunction including:

- Two forms of direct harm (price erosion and lost sales)
- Three forms of consequential harm (lost first mover advantage, reduced pipeline and reputational harm.)
- Irreparability of the harms.
- Balance of equities.
- Public interest.

[47] UTC 10-K, 2023, p. 16.

[48] Press Release, Liquidia Technologies, Inc., U.S. Federal Circuit Affirms Earlier PTAB Decision to Invalidate All Claims of United Therapeutics Patent No. 10,716,793 ('793 Patent), (12/20/2023) (LIQ_PH-ILD_00002639), available at https://liquidia.com/news-releases/news-release-details/us-federal-circuit-affirms-earlier-ptab-decision-invalidate-all

[49] UTC 10-K, 2023, p. 16.

[50] UTC 10-K, 2023, p. 16.

[51] Press Release, Liquidia Technologies, Inc., Liquidia Corporation Reports Full Year 2023 Financial Results and Provides Corporate Update (3/13/2024) (LIQ_PH-ILD_00001158), available at https://liquidia.com/news-releases/news-release-details/liquidia-corporation-reports-full-year-2023-financial-results

[52] UTC 10-K, 2023, p. 16.

[53] *United Therapeutics Corp. v. Liquidia Techs., Inc.*, Case No. 1:20-cv-00755-RGA, Doc. No. 479 (March 28, 2024).

29. In the following sections, I first discuss how Dr. Selck's opinions about the direct harms are refuted by UTC management's statements and forecasts, followed by sections specifically addressing each of his opinions.

6. EVIDENCE FROM UTC

30. Evidence from UTC's management indicates that Liquidia's sales of Yutrepia are not expected to affect UTC's sales of Tyvaso. In particular, the evidence shows that UTC does not believe that it will be harmed by Yutrepia's launch – much less Yutrepia's launch with a PH-ILD indication.

31. In the sections below, I first discuss a forecast of Tyvaso sales generated by UTC in [redacted] I then highlight statements from UTC's management discussing the expected effect of Yutrepia's launch. Finally, I analyze investor sentiment through an analysis of stock price movements for Liquidia and UTC around the dates of significant announcements.

6.1 UTC FORECAST

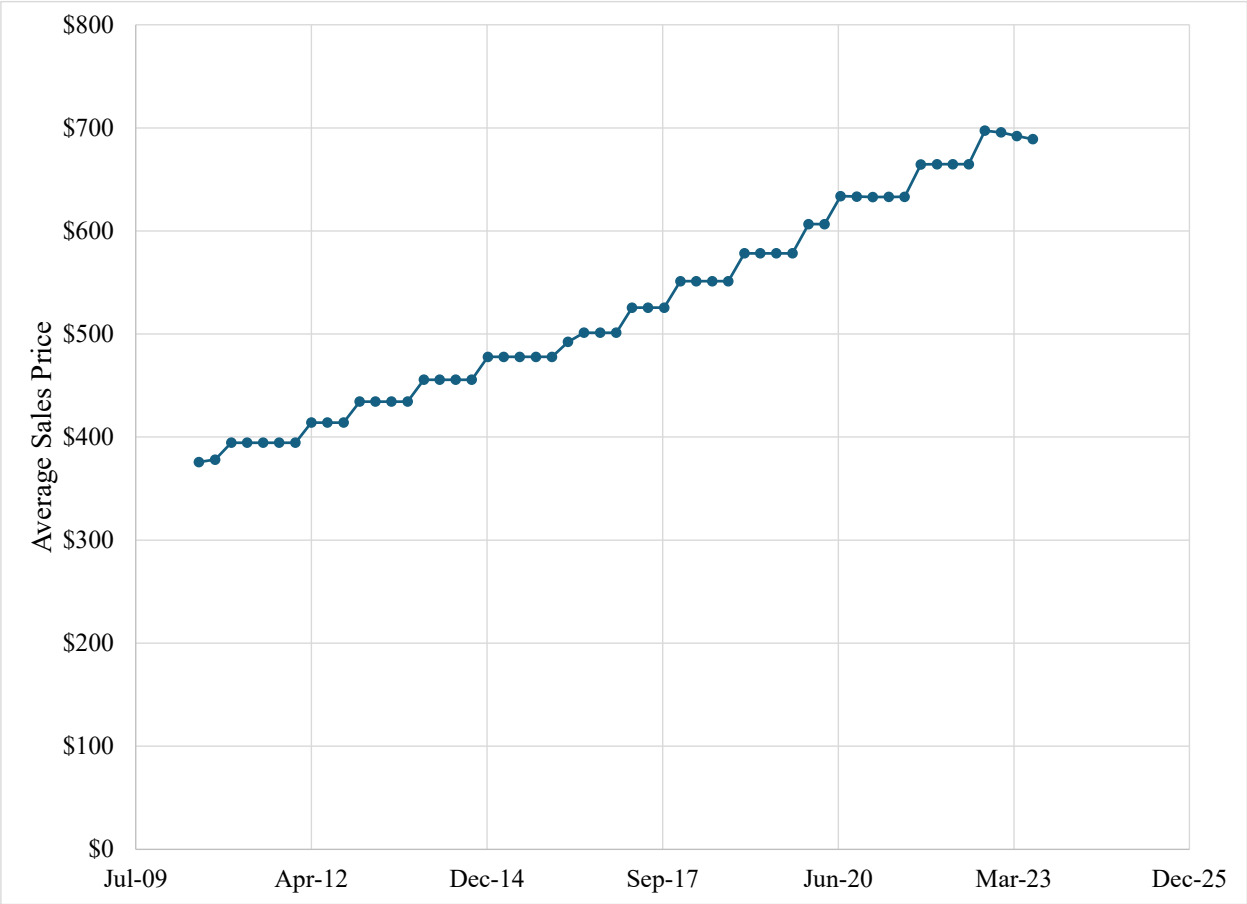
32. UTC's own [redacted] forecast demonstrates that [redacted] UTC would be able to [redacted].[54] For points of reference, the price of Tyvaso in 2023 was [redacted] and [redacted].[55]

33. The graph below shows that UTC's price for of a single dose of Tyvaso increased at 5% per year between 2009 and 2023:

[54] UTC_PH-ILD_009410–18 [United Therapeutics Tyvaso Forecast (2023-2035)] at 11, 14.

[55] UTC_PH-ILD_009410–18 [United Therapeutics Tyvaso Forecast (2023-2035)] at 11.

Chart 4: Tyvaso Average Sales Price per 1.74-MG Dose[56]



34. This growth is projected to continue uninterrupted. UTC forecasted that the prices of Tyvaso and Tyvaso DPI will [redacted]:

[56] Exhibit 3. United CMS ASP Data. This does not include Tyvaso DPI. I do not currently have information explaining why the price of Tyvaso declined from $697 per dose to $689 per dose between the fourth quarter of 2022 and the third quarter of 2023. Exhibits 3-6 as cited in this Declaration refer to documents bearing the following Bates Nos: LIQ_PH-ILD_00003004 (Exhibit 3); LIQ_PH-ILD_00003005 (Exhibit 4); LIQ_PH-ILD_00003006 (Exhibit 5); LIQ_PH-ILD_00003007 (Exhibit 6).

[redacted]

35. UTC is also forecasting growth in the [redacted].[58] UTC estimates that there are [redacted] in the United States.[59] Of these patients, UTC forecasted that in 2024, [redacted][60] Note that UTC projects a [redacted] and then [redacted]:

[57] Exhibit 4. UTC 2023 Forecast.

[58] UTC_PH-ILD_009410–18 [United Therapeutics Tyvaso Forecast (2023-2035)] at 10, 13, 16.

[59] UTC_PH-ILD_009410–18 [United Therapeutics Tyvaso Forecast (2023-2035)] at 10, 13.

[60] UTC_PH-ILD_009410–18 [United Therapeutics Tyvaso Forecast (2023-2035)] at 10.

[redacted]

36. UTC is, therefore, projecting [redacted].

37. As a result of [redacted], UTC is forecasting revenue from sales of Tyvaso for PAH and PH-ILD to [redacted]:

[61] Exhibit 4. UTC 2023 Forecast; UTC_PH-ILD_009410–18 at 10 [United Therapeutics Tyvaso Forecast (2023-2035)].

[redacted]

38. Notably, this forecasted [redacted].[63] [redacted]:[65]

[redacted]

39. This is the most recent forecast produced by UTC in this matter. In his deposition, Dr. Selck was [redacted].[66]

[62] Exhibit 4. UTC 2023 Forecast.

[63] UTC_PH-ILD_009410–18 [United Therapeutics Tyvaso Forecast (2023-2035)] at 16.

[64] 7.24.23 Liquidia Notice Letter to UTC.pdf.

[65] UTC_PH-ILD_009410–18 [United Therapeutics Tyvaso Forecast (2023-2035)] at 16 (highlighting added).

[66] Deposition of Frederic Selck, March 15, 2024 at 92:7–94:11.

6.2 UTC MANAGEMENT'S STATEMENTS

40. In contrast to Dr. Selck's opinion, UTC management has not projected any loss in revenue due to the launch of Yutrepia. In his deposition, Dr. Selck was asked about his conversations with UTC management and [redacted]:

[redacted]

41. In fact, UTC's public statements, before and after filing the present motion for a preliminary injunction, suggest that it does not expect any harm from the launch of Yutrepia.

42. In an earnings call on February 22, 2023 discussing UTC's results for the fourth quarter of 2022, UTC's Founder, Chairman & CEO, Martine Rothblatt was asked about the introduction of another potential option for treating PAH (sotaracept) and answered as follows:

> I will say that our revenue forecast is agnostic with regard to whether or not sotatercept is approved or not. In other words, we will remain confident about achieving the doubling of our revenues by 2025 without regard to its launch. There -- it's a very large and diversely treated patient population. Changes in treatment patterns are relatively slow and cautious especially other than frontline treatments such as like ETRAs or PD5s. So I'd be very, very skeptical that you would see an impact of sotatercept on United Therapeutics revenue profile or product uptake across the board, whether it's Remodulin, Tyvaso, Tyvaso DPI or Orenitram.
>
> **More broadly, the experience has been that when new agents have been introduced into the market, it has grown the market for all of the existing patients.** It's kind of like a market growth thing. You saw this with, for example, back in the day when we launched Remodulin and J&J's precursor Actelion launched bosentan, the treprostinil revenues did not shrink. In fact, they grew and then later on, when PDSs were introduced, the market for ETRAs, and treprostinil did not shrink. In fact, it grew, it grew quite a bit. And this has been just a continuous process, and it harkens back to the landmark number that you should keep in your mind that Michael Benkowitz mentioned in his remarks was 50,000, that's 5-0 thousand. That's the number of patients diagnosed with pulmonary hypertension. And all of these drugs have just like scratched the surface of being able to really treat the patients and get them back to a New York Heart Association Functional Class I or even Functional Class II level.

[67] Deposition of Frederic Selck, March 15, 2024 at 121:14–122:2.

> **So there is so much robust room for growth and improvement in pulmonary hypertension. We at United Therapeutics, welcome any new agent that can help the health of the pulmonary hypertension patient population.** And by the way, all that is with respect to WHO Group I pulmonary hypertension. So everything I just said, then you've got this other huge pool that Dr. Peterson opened up with her New England Journal article, WHO Group 111, 30,000 patients, that's 3-0 thousand, of which the only approved treatment right now is our Tyvaso drug.
>
> And I think sotatercept, I would love to see another good drug to help people with pulmonary hypertension. I don't think it's going to have any effect on our revenue growth.[68]

43. In an earnings call on May 3, 2023 discussing UTC's results for the first quarter of 2023, in her opening remarks, Dr. Rothblatt stated:

> Thank you, Dewey. Very excited to welcome everyone to another great quarter at United Therapeutics. We are thrilled to continue on course toward our mid-decade goals of 25,000 patients being treated for pulmonary hypertension and the doubling of our revenue run rate. This quarter, we moved toward those goals with double-digit revenue growth from first quarter '22 to first quarter '23. And that also includes, by the way, nearly 40% growth in our main growth driver, which is Tyvaso.
>
> **I think our double-digit growth rate remains a solid forecast even with the possibility of new FDA approvals of sotatercept or Liquidia.** The reason is that sotatercept has not even been tested in our main growth market of Group 3 pulmonary hypertension. Indeed, systemic drugs are generally contraindicated there due to them causing V/Q or ventilation-perfusion mismatch. In the disease sotatercept was tested in, Group 1 pulmonary arterial hypertension, we expect it to be complementary to either our Orenitram, Tyvaso or Remodulin products. So we don't forecast a realistic threat from sotatercept to our growth.
>
> (inaudible) **Liquidia, if approved, also does not challenge our projected double-digit growth.** It's because it's not a generic product, but is instead a strongly differentiated drug device product requiring 65% more drug to even match Tyvaso's effect based on their own clinical trial data.[69]

44. In an earnings call on August 2, 2023 discussing UTC's results for the second quarter of 2023, UTC was asked about the PH-ILD indication and UTC's President & COO, Michael Benkowitz answered:

---

[68] LIQ_PH-ILD_00001124–34 at 1132-1133 [Refinitiv Edited Transcript UTHR.0Q - Q4 2022 United Therapeutics Corp Earnings Call, February 22, 2023] (**Emphasis** added).

[69] NC-LIQ00491928–38 at 30 [Refinitiv Edited Transcript UTHR.0Q - Q1 2023 United Therapeutics Corp Earnings Call, May 3, 2023]. **Emphasis** added.

> [Q.] Maybe just as we think about penetration into the PH-ILD market, where do you think you stand now? And now that the therapy has been on the market for a couple of years in the indication, have your expectations for the size of this market changed at all?
>
> [A.] Sure. I think on penetration of the market, I think we're in low single digits. And I say think because I still -- and this is, I think, a question that was asked earlier that we just didn't have time to ask, but around the kind of the mix of the PAH and the PH-ILD. I mean the data coming in on the referrals is still not -- [not target], it's still a little dirty. So it's not still 100% clean in terms of what's Group 1 or what's Group 3. But I think based on kind of what we're seeing, it's -- I think it's fair to say that we're kind of in that low single digits of the PH-ILD market.
>
> And in terms of the size of the market, nothing's really changed in terms of our understanding of what that is. We kind of started out saying it's at least 30,000. We still think that that's accurate. You can talk to some KOLs, you'd think it's significantly higher than that, and that may be. But what we've said all along with the 30,000, I mean that's still a really good size market for us. And so we're really focused on continuing to penetrate in that market. And get -- as I said in my opening remarks, really kind of ramp up the screening of ILD patients to look for pulmonary hypertension.[70]

45. At a March 5, 2024 conference, Mr. Benkowitz was asked about how UTC sees Liquidia as a potential competitor and whether it was factored into UTC's business model. Mr. Benkowitz responded that based on discussions with payers (e.g., insurance companies), UTC believes that Tyvaso and Yutrepia will be competing on "a level playing field" where the doctor and patient will decide which treatment to use:

> Did you say why would Liquidia become the -- I think I believe -- we believe Tyvaso will continue to be the preferred agent for very -- I mean the big one is that we've got 2 years of patient data, thousands of patients on the product. The patients are -- satisfaction level is incredibly high both by the physicians and by the patients. And so they have that experience with our product, which is incredibly helpful.
>
> I think -- we think the convenience of our device as a differentiator. Ours is one (inaudible) per session. Their's 2. Ours doesn't require cleaning. Their's does. We don't have a max label dose. And so we just think, all in all, the patients and the physicians are going to prefer our product. We think the other thing that's attractive about our devices are just what's called a low-flow device and so that means that it requires less patient effort to actually breed the drug.
> And then as a result of that, that property or that characteristic. The drug is actually getting deeper into the lungs. So what you see with a high flow device, which is what their device is. So we think all in all, the totality of the

[70] LIQ_PH-ILD_00001146–57 at 1154 - 1155 [Refinitiv Edited Transcript UTHR.0Q - Q2 2023 United Therapeutics Corp Earnings Call, August 2, 2023].

> characteristics of our device are going to be preferred by physicians and patients.
>
> **And then on the payer side, you were in these discussions right now with payers and kind of working that out. But I think we're feeling increasingly confident that there's not going to be preference, so it's going to be a level playing field. So it's really going to be up to the patient and the physician, and we feel confident about how we're going to do there.** [71]

46. UTC management, therefore, based on statements over the past several years, including after filing this motion for a preliminary injunction, does not appear to believe that its revenue is threatened by the launch of Yutrepia. It is forecasting and publicly stating that it still expects "double-digit" revenue growth for UTC even after Yutrepia's launch.

6.3 STOCK PRICE ANALYSIS

47. Dr. Selck claims that:

> Recent stock price trends further demonstrate the competitive relationship between United and Liquidia. Around December 20, 2023, when the Federal Circuit decided to invalidate all claims of United's U.S. Patent No. 10,716,793, United's stock price dropped significantly and Liquidia's stock price increased significantly. From an economic perspective, United's stock price decreasing and Liquidia's stock price increasing around this event demonstrate that the market views Yutrepia and the Tyvaso products to be close competitors. While I understand that U.S. Patent No. 10,716,793 is not the basis for United's request for injunctive relief in this matter, the stock price behavior is indicative of investor expectations of direct competition between Yutrepia and the Tyvaso products.[72]

48. While I agree with Dr. Selck that Tyvaso and Yutrepia are competitors, his evidence from the stock market is both flawed and incomplete.

49. His analysis is flawed for several reasons:

- Use of a four-day event window
- Failure to normalize for overall market movements
- Failure to analyze whether the movement is statistically significant.

50. The four-day event window is far longer than the market requires to respond to news and, therefore, will incorporate movements unrelated to the news. In particular, Dr. Selck's four-day window

[71] LIQ_PH-ILD_00001162–71 at 1167 [Refinitiv StreetEvents, Edited Transcript, UTHR.0Q - United Therapeutics Corp at TD Cowen Health Care Conference, March 05, 2024, p. 6] **(emphasis** added).

[72] Selck Declaration, ¶61.

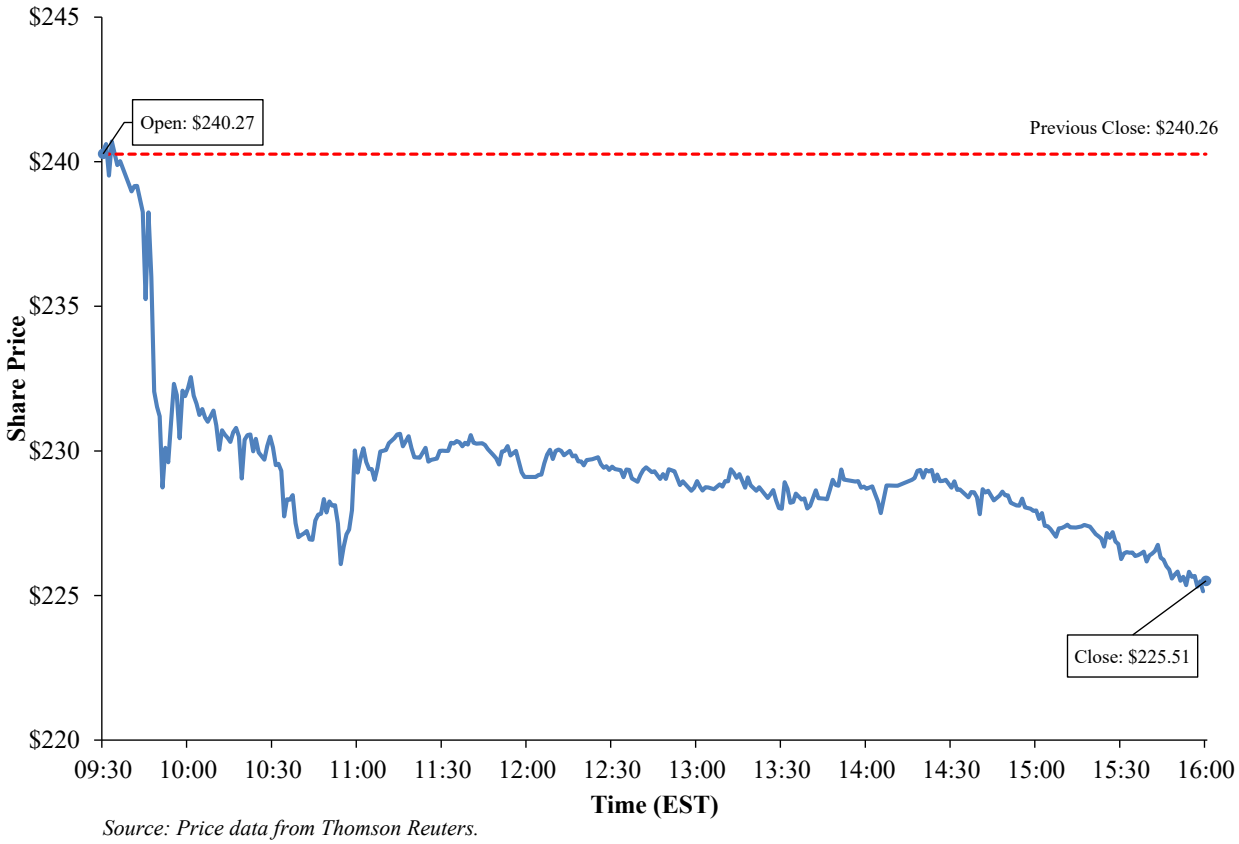
spans across a weekend. UTHR's price changed by -6.1%, -3.2% 0.3%, -1.2% respectively on the four days including and after December 20, 2023.[73] There is no reason to believe that UTC's stock price increased by 0.3% on the third day due to the news that the Federal Circuit decided to invalidate one of its patents. Restricting the event window to just December 20, 2023 suggests that UTC's stock price declined by 6.1% due to the news.

51. In fact, the news that the Federal Circuit had invalidated all claims of the '793 Patent was apparently incorporated into UTC's stock price within fifteen minutes. The Federal Circuit typically publishes its opinions between 8:30am and 11:00am (Eastern) each day.[74] The intraday chart of UTHR shows that it first traded at 9:30am at $240 and fell below $230 by 9:45am, then drifted down to close at $225 as shown in the chart below:

[73] Exhibit 5.2.

[74] U.S. Court of Appeals for the Federal Circuit, Opinions and Orders (LIQ_PH-ILD_00002788), available at https://cafc.uscourts.gov/home/case-information/opinions-orders/.

Chart 8: UTHR Intraday Price, 20 December 2023[75]



Source: Price data from Thomson Reuters.

52. Therefore, there is no basis for Dr. Selck to use a four-day event window when it appears that the news had been incorporated into UTC's stock price within fifteen minutes.

53. Dr. Selck also fails to normalize for overall market movements. For example, on the day of the announcement, December 20, 2023, the overall NASDAQ 100 index declined by 1.5%. Thus, the price movement on December 20, 2023 that might be due to the news is only -4.6%.[76]

54. Dr. Selck also does not investigate whether this movement on December 20, 2023 is statistically significant. Stock prices move every day due to a wide variety of factors. Statisticians use a significance test to see whether the stock price movement on any single day is more than two standard deviations away from the average.[77]

[75] Exhibit 6. Intraday Chart UTHR.

[76] Exhibit 5.2.

[77] A standard deviation is a measure of the spread of data around the mean. Two standard deviations away from the mean indicates that the data point is unusually far from the mean and may be significantly different from the

55. Dr. Selck's work is incomplete in the sense that he only examines this one event without considering UTC's and Liquidia's stock price movements around other events.

56. My more-sophisticated analysis of UTC's and Liquidia's stock prices indicates that there was a statistically significant change in both UTC's and Liquidia's stock prices on December 20, 2023.[78] Note that I am not claiming that my analysis is definitive. Doing a full and complete analysis of any particular event on stock prices is a lengthy and detailed endeavor involving a careful examination of the exact time when the news became available, the typical amount of time it takes for the market to react to the news (the event window) and an analysis of confounding factors that could have caused or contributed to the price movement.[79] In this case, given the time constraints, I believe my analysis is generally accurate but additional evidence could be brought to my attention that might lead me to change my conclusions.

57. My more fulsome analysis of news that might have affected both UTC (ticker symbol "UTHR") and Liquidia (ticker symbol "LQDA") stocks indicates that UTC's stock price is less sensitive to announcements than Liquidia's. In the table below figures in red indicate that the stock price movement was statistically significant.

average. I am using two standard deviations here because that is a typical significance test at the 95% confidence level.

[78] Exhibit 5.1.

[79] A confounding factor in statistics is an additional factor that could affect the stock price – e.g. perhaps an announcement by some other pharmaceutical company that would affect investor's perceptions of either UTC's or Liquidia's prospects.

Table 9: Normalized Stock Price Changes on Selected Dates[80]

Date	Event	LQDA	UTHR
31-Mar-2021	Tyvaso (nebulized) receives FDA approval for PH-ILD indication	5.9%	1.1%
01-Apr-2021	UTC announces Tyvaso FDA approval for PH-ILD	2.6%	15.0%
05-Nov-2021	Yutrepia receives tentative FDA approval for PAH indication	-4.2%	0.4%
08-Nov-2021	Liquidia announces tentative FDA approval for PAH indication	4.1%	-0.1%
23-May-2022	Tyvaso DPI receives FDA approval	-18.8%	11.6%
24-May-2022	UTC announces Tyvaso DPI FDA approval	-28.3%	4.2%
19-Jul-2022	PTAB issues decision finding all claims of '793 Patent unpatentable	45.3%	-1.1%
30-Aug-2022	Judge denies stay of decision on '793 Patent pending PTAB appeal	-30.4%	0.7%
31-Aug-2022	Court ruling against '793 Patent	7.2%	3.5%
01-Sep-2022	Liquidia shareholder call regarding ruling on '793 Patent	-15.8%	-0.2%
20-Dec-2023	Federal Circuit affirms PTAB decision to invalidate '793 Patent	35.7%	-6.1%

58. The table above indicates that UTC's stock generally was unaffected by rulings in the prior patent case – other than the December 20, 2023 announcement – while it was positively affected by announcements relating to approval of Tyvaso DPI and the PH-ILD indication. In particular, the PTAB decision on July 19, 2022 invalidating all claims of the '793 Patent does not appear to have affected UTC's stock price; which is a contrast to the Federal Circuit ruling on December 20, 2023. Additionally, the news that Yutrepia had received FDA approval did not affect UTC's stock price – nor did it significantly affect Liquidia's stock price.

59. Liquidia's stock, on the other hand, has been significantly affected by rulings in the prior patent case as well as the launch of Tyvaso DPI.

7. PRICE EROSION

60. Dr. Selck acknowledged, and confirmed by conversations with UTC that, to the extent there is any price erosion, it will happen due to Yutrepia's launch with or without a PH-ILD indication.[81] Dr. Selck has not done any analysis or offered any opinion about the extent of any price erosion due solely to Yutrepia's launch with a PH-ILD indication.

[80] Exhibit 5.1. "Normalized" figures account for overall market movements.

[81] Deposition of Frederic Selck, March 15, 2024 at 62:11–16.

61. Dr. Selck opines that launching with the PH-ILD indication will cause more price erosion than launching with just the PAH indication:

> Even though there may be some price erosion following Yutrepia's launch in the PAH indication, it will be materially greater if Yutrepia is permitted to launch for both PAH and PH-ILD.[82]

62. Dr. Selck's opinion is based on a general discussion of price erosion in pharmaceuticals and an undocumented interview lasting less than an hour of a UTC employee who generally claimed [redacted]. Dr. Selck reviews the history of price declines for Hepatitis C treatments[83], and PSCK9 Inhibitors[84] after the entry of competitors. However, Dr. Selck then opines that these examples are not instructive in the present case:

> While the outcome of direct competition between products in other markets (e.g., PCSK9 inhibitors or Hepatitis C treatments) may provide insight as to the types of harm that United is likely to suffer absent injunctive relief in this case (i.e., price erosion, lost sales, and lost market share), as well as demonstrating that such harms can be significant, the PH-ILD market is unique such that the experience of other products is a deficient benchmark for quantifying the full extent of the impact of Liquidia's infringement on United. The only products indicated to treat PH-ILD are Tyvaso and Tyvaso DPI (see Section 3). This means there are no competitive benchmarks available in the PH-ILD marketplace.[85]
> …
> A similar logic applies to other potential benchmarks. There is no comparable that is a close enough comparator to the circumstances of Tyvaso and Tyvaso DPI.[86]

63. I agree with Dr. Selck that price erosion can happen with competitive entry and that it does appear to have happened in the two cases he cites. I also agree with Dr. Selck that no further conclusions can be drawn from his two examples. However, that does not answer the critical question of whether, or if, price erosion will happen if Yutrepia is allowed to enter the market with a PH-ILD indication.

64. The evidence Dr. Selck proffers for price erosion specifically linked to launching Yutrepia with a PH-ILD indication comes entirely from a single, undocumented interview with UTC's "Associated [sic]

[82] Selck Declaration, ¶16.

[83] Selck Declaration, ¶¶77–81, 92–93.

[84] Selck Declaration, ¶¶82–84, 92–93.

[85] Selck Declaration, ¶124.

[86] Selck Declaration, ¶127

Vice President of Managed Markets and Reimbursement", David Barton.[87] Dr. Selck relies on Mr. Barton for the following assertions:

[redacted][88]

…

…

…

[redacted][89]

…

[redacted]ucts.[90]

…

[redacted][91]

…

[redacted][92]

65. I have been unable to ascertain from Dr. Selck's conclusory statements from his undocumented conversation with Mr. Barton regarding [redacted]. In particular, Dr. Selck's description of Mr. Barton's only opinion that relates specifically to launching with the PH-

[87] Selck Declaration, ¶10. Deposition of Frederic Selck, March 15, 2024 at 28:21 – 29:3.

[redacted]

[88] Selck Declaration, ¶62.

[89] Selck Declaration, ¶64.

[90] Selck Declaration, ¶66.

[91] Selck Declaration, ¶73.

[92] Selck Declaration, ¶74.

ILD indication is that UTC [redacted][93] This is a stated expectation about [redacted] due to Yutrepia launching with the PH-ILD indication.

66. In contrast to Dr. Selck's claims about price erosion, Mr. Barton [redacted]

[redacted]

[redacted][94]

67. Furthermore, Dr. Selck acknowledged that price erosion for Tyvaso is not linked just to the PH-ILD indication but will occur because of Liquidia's entry into the market for the PAH indication:

[redacted]

[redacted][95]

[93] Selck Declaration, ¶73.

[94] Deposition of Frederic Selck, March 15, 2024 at 81:3–10.

[95] Deposition of Frederic Selck, March 15, 2024 at 41:14–42:21 (**emphasis** added).

…

[redacted][96]

68. Dr. Selck's distinction between discounts for PH-ILD indications and PAH indications is disingenuous in light of his acknowledgment that Medicare does not allow differentiating prices by indication and that it can be difficult to identify PH-ILD patients. [97]

69. In summary, according to UTC's own documents and statements, price erosion due to Yutrepia launching with a PH-ILD indication does not appear to be a discernible threat to UTC. While price erosion can occur in theory, neither of Dr. Selck's examples are useful here. His only evidence supporting price erosion specifically due to Yutrepia launching with a PH-ILD indication comes from a single, undocumented conversation with a UTC employee. But that conversation only indicated Mr. Barton's belief that [redacted].

8. LOST SALES

70. Dr. Selck's evidence for lost sales does not address the critical distinction between sales lost because Yutrepia is being sold with for the PAH indication and sales lost because Yutrepia is being sold with for the PH-ILD indication. For example, Dr. Selck states:

> Thus, Yutrepia entering the market and receiving favorable placement over the Tyvaso products will result in lost sales for the Tyvaso products.[98]
> …
> Even assuming similar coverage for the Tyvaso products and Yutrepia, sales that Yutrepia earns are likely to reflect at least some lost sales for the Tyvaso products.[99]

[96] Deposition of Frederic Selck, March 15, 2024 at 62:6–16.

[97] Selck Declaration, ¶¶18, 40.

[98] Selck Declaration, ¶85.

[99] Selck Declaration, ¶86.

71. Dr. Selck's opinion about lost sales relies on general statements about competition between Tyvaso and Yutrepia and are not specific to the PH-ILD indication:

> [redacted][100]
> …
> Harm to sales is also likely to be significant because Yutrepia's market entrance places United in the position of having to choose between maintaining its marketing efforts for the Tyvaso products, which will likely also aid Liquidia as inadvertent marketing for Yutrepia given the drug similarities, or reducing its marketing efforts in order to avoid that outcome.[101]

72. Dr. Selck then asserts that these same harms are applicable to the PH-ILD Market:

> The extent of lost unit sales and market share for the Tyvaso products due to Liquidia's infringement will be significant because the PH-ILD market is in its early stages and expected to grow.[102]

73. The lost sales that Dr. Selck asserts here are attributable to Yutrepia's sales – not just Yutrepia's sales with a PH-ILD indication. Dr. Selck realizes that these are two separate questions but offers the unsupported opinion that:

> Even though there will be some lost unit sales and market share following Yutrepia's launch in the PAH indication, lost sales and market share will be materially greater if Yutrepia is permitted to launch for both PAH and PH-ILD.[103]

74. It is not clear what Dr. Selck means by "materially greater" — but that is the crux of the question. As a matter of basic economics, Tyvaso will be competing with Yutrepia for at least the PAH indication and will, therefore, likely lose some sales to Yutrepia. The real question is how many more sales, if any, will Tyvaso lose as a result of Yutrepia having a PH-ILD indication? Dr. Selck has provided no basis on which one could conclude that the difference will be "material."

75. Dr. Selck's opinions on lost sales appear to assume that every Yutrepia patient will be a lost Tyvaso patient. Dr. Selck does not offer any evidence to support this conclusion, and it is questionable given that UTC forecasts it [redacted][104] Consistent with Dr. Rothblatt's commentary that new agents will expand the market for

[100] Selck Declaration, ¶86

[101] Selck Declaration, ¶87.

[102] Selck Declaration, ¶91.

[103] Selck Declaration, ¶94.

[104] UTC_PH-ILD_009410–18 at 10, 13 [United Therapeutics Tyvaso Forecast (2023-2035)].

pulmonary hypertension therapies and UTC's [redacted], the evidence suggests that Yutrepia could serve some patients that Tyvaso would not be serving.

76. Thus, Dr. Selck's opinion that there will be a material difference between UTC's sales if Yutrerpia launches with a PH-ILD indication is not only unsupported but contradicted by UTC's management statements and forecasts.

9. PH-ILD MARKET

77. Dr. Selck opines that there is a separate market for PH-ILD:

> The size of the PH-ILD market will be driven in part by uncertain PH-ILD diagnosis rates, which makes long-term market size infeasible to determine.[105]
> …
> It also remains unclear how Yutrepia's entry into the PH-ILD market…[106]

78. Dr. Selck has offered multiple definitions of the market – none of which pass scrutiny.

79. In his declaration, Dr. Selck defines this separate market as "treprostinil-based inhalation products that are FDA-approved for treating … PH-ILD."[107] Also in his declaration, he describes it as "the only treatments approved for PH-ILD."[108] In his deposition, Dr. Selck defined the market as [redacted]"[109] Under any definition, he opines that UTC is the only company in the market.[110]

80. Yet Dr. Selck does not provide any evidence that, under any definition, PH-ILD is a separate market. Nor did Dr. Selck perform any analysis indicating that such a market existed.[111] In particular, I

[105] Selck Declaration, ¶17.

[106] Selck Declaration, ¶18.

[107] Selck Declaration, ¶15.

[108] Selck Declaration, ¶85.

[109] Deposition of Frederic Selck, March 15, 2024 at 72:15–20.

[110] Selck Declaration, ¶15. "Currently, the only treprostinil-based inhalation products that are FDA-approved for treating PAH and PH-ILD are Tyvaso (a nebulized liquid for inhalation) and Tyvaso DPI (a dry powder inhalation) (collectively, "the Tyvaso products"), developed by United."

[111] Deposition of Frederic Selck, March 15, 2024 at 74:17–75:9.

[redacted]

would have expected someone with Dr. Selck's background and training to have used the SSNIP test to determine whether there is a separate PH-ILD Market. Dr. Selck is aware of the SSNIP test, but never thought to apply it.[112] In fact, this proposed market fails the SSNIP test as I discuss in the following paragraphs.

81. The SSNIP test is part of the "hypothetical monopolist test" and is described by the U.S. Department of Justice as:

> The Hypothetical Monopolist/Monopsonist Test ("HMT") evaluates whether a group of products is sufficiently broad to constitute a relevant antitrust market. To do so, the HMT asks whether eliminating the competition among the group of products by combining them under the control of a hypothetical monopolist likely would lead to a worsening of terms for customers. The Agencies generally focus their assessment on the constraints from competition, rather than on constraints from regulation, entry, or other market changes. The Agencies are concerned with the impact on economic incentives and assume the hypothetical monopolist would seek to maximize profits.
>
> When evaluating a merger of sellers, the HMT asks whether a hypothetical profit-maximizing firm, not prevented by regulation from worsening terms, that was the only present and future seller of a group of products ("hypothetical monopolist") likely would undertake at least a small but significant and non-transitory increase in price ("SSNIP") or other worsening of terms ("SSNIPT") for at least one product in the group.[113]

82. Dr. Selck provides evidence that shows that the proposed PH-ILD Market fails the SSNIP test. UTC is actually a monopolist in Dr. Selck's proposed PH-ILD Market – it sells both Tyvaso and Tyvaso DPI into this proposed market. In fact, when Tyvaso was approved for the PH-ILD indication, there was

[redacted]

[112] Deposition of Frederic Selck, March 15, 2024 at 73:3–15.

[redacted]

[113] U.S. Dep't of Justice & FTC Merger Guidelines (2023) (LIQ_PH-ILD_00001073), available at https://www.justice.gov/d9/2023-12/2023%20Merger%20Guidelines.pdf, pp. 41–42.

no change in price.[114] The best that Dr. Selck can do is speculate that UTC might theoretically be able to charge a price premium for PH-ILD patients in the future:

> In theory, to the extent that United markets the Tyvaso products differently to prescribers for PAH and prescribers for PH-ILD, in the presence of an injunction, United could potentially segment the market between PH-ILD and PAH such that it preserves a higher price for PH-ILD and competes on price for PAH, thereby potentially mitigating the harms from price erosion due to Yutrepia's infringement.[115]

83. However, Dr. Selck also describes how UTC has no ability to charge different prices for Tyvaso for a PH-ILD indication:

> The Average Sales Price ("ASP") used by Medicare for physician reimbursement depends on the rebates or discounts granted across all sales of Tyvaso, regardless of indication. Absent an injunction, competition across both PAH and PH-ILD indications would result in one overall downward trend for Tyvaso's ASP.[116]

84. Without the ability to charge a different price for Tyvaso for the PH-ILD indication, there can be no price increase solely for this "PH-ILD Market" and this proposed market, thereby, fails the SSNIP test.

85. In his deposition, Dr. Selck claimed that [redacted]:

[redacted]

[114] Exhibit 3. United CMS ASP Data. This does not include Tyvaso DPI. I do not currently have information explaining why the price of Tyvaso declined from $697 per dose to $689 per dose between the fourth quarter of 2022 and the third quarter of 2023.

[115] Selck Declaration, ¶72.

[116] Selck Declaration, ¶18.

[redacted][117]

86. However, these proposed market definitions suffer from at least three significant problems. First, observability does not remove the need to establish whether it is a market. Second, patients are typically not the buyers of the drugs. Describing the patients as the market ignores the reality that doctors, and often the insurance companies (including Medicare/Medicaid) determine whether a patient may be prescribed drugs like Tyvaso and Yutrepia. Third, Dr. Selck acknowledges that, far from being "observable" doctors have difficulty diagnosing PH-ILD. For example, in his declaration, Dr. Selck describes this difficulty:

> Due to its overlap with other diseases, "[t]he diagnosis of PAH is also one of exclusion, meaning that PAH is only diagnosed when other causes of pulmonary hypertension have been ruled out and there seems to be no known cause of the hypertension."[118]
> …
> Interstitial lung diseases ("ILDs") are a group of disorders that can cause scarring in the lungs, affecting the lungs' ability to carry oxygen and making harder for a patient to breathe normally. It is "common for ILD patients to also develop" PH. PH is usually suspected when a patient's symptoms are "out of proportion to the severity of the patient's ILD." As mentioned in Section 3.2.1, there are many tests that can be utilized to rule out other diseases—the most common currently being an echocardiogram—leaving PH as the last remaining possible explanation for a patient's symptom.[119]

87. Dr. Selck's comments above are further supported by statements in UTC's marketing plans about the difficulties of identifying and getting treatment to PH-ILD patients:

[redacted]

[117] Deposition of Frederic Selck, March 15, 2024 at 74:17–75:17. *See also*, 167:8–14 [redacted]

[118] Selck Declaration, ¶36.

[119] Selck Declaration, ¶40.

[redacted][120]

88. Dr. Selck confirmed these opinions in his deposition:

[redacted][121]

89. This difficulty was confirmed in a conversation with Dr. Channick in which he described how patients exist on a spectrum between PH-ILD and PAH, thereby making a definitive diagnosis difficult.[122]

90. Dr. Selck further opines that identifying PH-ILD patients is a [redacted]:

[redacted][123]

91. Thus, Dr. Selck makes the contradictory claims that the PH-ILD Market is defined by observable characteristics and that it can be hard to tell whether a patient has PH-ILD. Simply identifying the "observable" characteristic is a rate-limiting step.

92. Dr. Selck also claims that there is a separation between his PAH Market and PH-ILD Market because writing prescriptions for PH-ILD off label would be rejected by the insurers:

[redacted]

[120] UTC_PH-ILD_009201–32 at 11. [2023 Business Planning, UT Marketing]

[121] Deposition of Frederic Selck, March 15, 2024 at 63:15–64:8.

[122] Conversation with Dr. Richard Channick, March 28, 2024.

[123] Deposition of Frederic Selck, March 15, 2024 at 131:18–132:8.

[redacted][124]

93. However, Dr. Selck also acknowledges that other drugs are used for PH-ILD even though that use is off-label:

[redacted][125]

94. Indeed, Dr. Nathan explained in his deposition that he [redacted]

[redacted][126]

95. Thus, Dr. Selck's claim that off-label prescriptions would not enter the proposed PH-ILD Market is contradicted by the evidence. In fact, given the difficulty of distinguishing between PAH and PH-ILD, a patient with PH-ILD could be diagnosed with PAH, thereby making the use on-label.[127]

[124] Deposition of Frederic Selck, March 15, 2024 at 69:20–70:11.

[125] Deposition of Frederic Selck, March 15, 2024 at 70:13–71:11.

[126] Deposition of Steven Nathan, March 10, 2024 at 89:7–13, 93:14–94:8.

[127] Conversation with Dr. Richard Channick, March 28, 2024.

96. Thus, the evidence is very clear that there is no separate PH-ILD Market under any definition proposed by Dr. Selck. Dr. Selck implicitly assumes that there is a significant population of patients who unambiguously have PH-ILD and are attended by a doctor who will not prescribe off-label. Such a market fails the SSNIP test. PH-ILD patients – to the extent they can be identified – are typically not the decision makers authorizing the purchase of drugs to treat PH-ILD and are hard to identify absent invasive procedures.

97. This assumption that there is a separate PH-ILD Market is central to many of Dr. Selck's opinions including:

> … Tyvaso products will experience price erosion as well as lost unit sales and market share in both the PAH and PH-ILD markets...[128]
>
> …the PH-ILD indication remains a nascent market. The size of the PH-ILD market…[129]
>
> …Liquidia will directly compete with United in the PAH and PH-ILD markets.[130]
>
> …allowing Yutrepia to enter the PH-ILD marketplace prematurely will harm drug development incentives in a growing therapeutic space.[131]
> …
> …absent an injunction, United will have to offer greater discounts and price concessions due to Yutrepia's infringement and entry into the PH-ILD marketplace. Accordingly, Liquidia's entry into the PH-ILD market will cause significant, lasting price erosion.[132]
> …
> the Tyvaso products and Yutrepia will directly compete in the PH-ILD market[133]
> …
> If an injunction is not granted and Yutrepia is later forced to withdraw from the PH-ILD market, United will suffer harm as this nascent market develops.[134]
> …
> Liquidia's premature entry into the PH-ILD market will irreparably harm United through negating United's first mover advantage benefits including brand recognition.[135]

[128] Selck Declaration, ¶15.

[129] Selck Declaration, ¶17.

[130] Selck Declaration, ¶60.

[131] Selck Declaration, ¶21.

[132] Selck Declaration, ¶62.

[133] Selck Declaration, ¶86.

[134] Selck Declaration, ¶90.

[135] Selck Declaration, ¶96.

> …
> It also remains unclear how harm suffered by United due to Yutrepia's entry into the PH-ILD market would be fully quantified (and hence compensated) given how drug reimbursement is computed under Medicare.[136]
> …
> Due to the complexity of the PH-ILD market, standard methodologies and/or benchmarks for evaluating but-for sales—such as sales forecasts, other products and comparables, and imputed market shares—are deficient.[137]
> …
> the lost profits to United arising from Liquidia's entry in the PH-ILD marketplace are likely to be significantly larger than the profits gained by Liquidia from entering the PH-ILD marketplace.[138]
> …
> United's investments in the Tyvaso products and in developing the PH-ILD market exceed Liquidia's investments.[139]
> …
> Liquidia's entry into the PH-ILD market threatens not only the success of the Tyvaso products, but also United's company-wide success.[140]

98. Because there is no separate PH-ILD Market, all of Dr. Selck's conclusions regarding harm that UTC will suffer in the PH-ILD Market are incorrect.

10. LOST FIRST MOVER ADVANTAGE

99. Dr. Selck opines that UTC will lose its first mover advantage absent a preliminary injunction:

> Through its investments in the Tyvaso products, United has engaged in effort to increase its brand recognition for the Tyvaso products among both physicians and patients. United has also benefited from first mover advantages in the PH-ILD market, including brand recognition and stickiness due to patient familiarity.[141]
> …
> Liquidia's premature entry into the PH-ILD market will irreparably harm United through negating United's first mover advantage benefits including brand recognition. United has expended time and expense developing the Tyvaso products and obtaining approval for the Tyvaso products to treat PH-ILD, thereby creating the PH-ILD market segment. As such, United is

[136] Selck Declaration, ¶113.

[137] Selck Declaration, ¶118.

[138] Selck Declaration. ¶137.

[139] Selck Declaration, ¶149.

[140] Selck Declaration, ¶158.

[141] Selck Declaration, ¶95.

> establishing the brand name of Tyvaso as synonymous with innovation and with filling the unmet need for a treatment for PH-ILD.[142]

100. First, as described previously, there is no separate PH-ILD Market, therefore, his construct is flawed from the beginning. Second, Dr. Selck has not provided any evidence that "United is establishing the brand name of Tyvaso as synonymous with innovation" — that is simply an assertion without any support. [143]

101. Furthermore, while the idea of a first mover advantage has conventional wisdom behind it, careful reviews indicate that it is not always a given. In fact, the paper Dr. Selck cites most heavily concludes that there are disadvantages to being the first mover:

> We first consider theoretical models and empirical evidence on three general categories in which first-mover advantage can be attained: leadership in product and process technology, preemption of assets, and development of buyer switching costs. We then examine potential *disadvantages* of first-mover firms (or conversely, relative advantages enjoyed by late-mover rivals). These include free-rider problems and a tendency toward inertia or sluggish response by established incumbents.[144]

102. Another paper not cited by Dr. Selck describe the first mover advantage as a myth:

> **The Myth of First Mover Advantage**
> Conventional wisdom would have us believe that it is always beneficial to be first – first in, first to market, first in class. The popular business literature is full of support for being first and legions of would-be business leaders, steeped in the Jack Welch school of business strategy, will argue this to be the case. The advantages accorded to those who are first to market defines the concept of First Mover Advantage (FMA).
>
> We outline why this is not the case, and in fact, that there are conditions of applicability in order for FMA to hold (and these conditions often do not hold). We also show that while there can be advantages to being first, from an economic perspective, the costs generally exceed the benefits, and the full economics of FMA are usually a losing proposition. Finally, we show that increasingly, we live in a world where FMA is eclipsed by innovation and format change, rendering the FMA concept obsolete (i.e. strategic obsolescence).[145]

103. Another paper not cited by Dr. Selck concludes that:

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[142] Selck Declaration, ¶96.

[143] Selck Declaration, ¶96.

[144] UTC_PH-ILD_002310–28 at 11. [Lieberman, Marvin B. and David B. Montgomery, "First-Mover Advantages," *Strategic Management Journal* 9, (1988): 41–58, at 41] (emphasis in original).

[145] IHS Consulting, "The Myth of First Mover Advantage", February 2012.

> Some management concepts have such intuitive appeal that their validity is almost taken for granted. First-mover advantage is one such concept. Although the fate of its most-convinced adherents, the dot-coms, offers a cautionary lesson, managers' faith that first-mover status brings important competitive advantages, even when network effects are not available to accelerate and entrench it, remains undiminished. Business executives from every kind of company maintain, almost without exception, that early entry into a new industry or product category gives any firm an almost insuperable head start. But for every academic study proving that first-mover advantages exist, there is a study proving they do not. While some well-known first movers, such as Gillette in safety razors and Sony in personal stereos, have enjoyed considerable success, others, such as Xerox in fax machines and eToys in Internet retailing, have failed. We have found that the differences in outcome are not random-that first-mover status can confer advantages, but it does not do so categorically. Much depends on the circumstances in which it is sought.[146]

104. The fundamental question of why innovators frequently do not reap the benefits of their innovation was addressed in a highly regarded paper written by Dr. David Teece in 1986. Dr. Teece wrote:

> This paper attempts to explain why innovating firms often fail to obtain significant economic returns from an innovation, while customers, imitators and other industry participants benefit. Business strategy – particularly as it relates to the firm's decision to integrate and collaborate – is shown to be an important factor. The paper demonstrates that when imitation is easy, markets don't work well, and the profits from innovation may accrue to the owners of certain complementary assets rather than to the developers of the intellectual property. This speaks to the need, in certain cases, for the innovating firm to establish a prior position in these complementary assets. The paper also indicates that innovators with new products and processes which provide value to consumers may sometimes be so ill positioned in the market that they necessarily will fail. The analysis provides a theoretical foundation for the proposition that manufacturing often matters, particularly to innovating nations. Innovating firms without the requisite manufacturing and related capacities may die, even though they are the best at innovation.[147]

105. While a first mover advantage is a possibility, it does not appear that, if it exists for UTC's marketing of Tyvaso for PH-ILD, it is significant. The Lieberman article on first mover advantages cited heavily by Dr. Selck suggests that first mover advantages arise from three sources:

- leadership in product and process technology,
- preemption of assets

[146] Suarez, Fernando and Gianvito Lanzolla, "The Half-Truth of First-Mover Advantage," *Harvard Business Review*, April 2005 [(LIQ_PH-ILD_00002511].

[147] Teece, David, "Profiting from technological innovation: Implications for integration, collaboration, licensing and public policy," *Research Policy* 15, (1986): 285–305, at 285.

- development of buyer switching costs[148]

106. The first two sources of first mover advantage do not appear to apply to Tyvaso because Liquidia has, at least arguably, a superior product and there are no assets to preempt here. The final category – the "development of buyer switching costs" appears weak at best. Dr. Selck refers to brand recognition arising from Tyvaso's sales using the PH-ILD indication.[149] However, in a highly regulated environment with a focus on product efficacy and price, it is hard to see how brand recognition would lead to significant buyer switching costs.

107. In summary, while Dr. Selck alludes to the conventional wisdom of a first mover advantage, that is overly simplistic. First mover advantage can exist and be valuable under certain conditions – none of which appear to be met here.

11. Reduced Pipeline Investment

108. Dr. Selck describes reduced pipeline investment as an indirect harm to UTC:

> In addition to the direct harm to United arising from price erosion, lost unit sales, and lost market share, the reduced revenues from these harms will inhibit United's ability to invest in ongoing development efforts for its pipeline drug candidates and products, which include novel drugs to treat PAH as well as organ manufacturing projects for treating end-stage organ disease.[150]

109. As I address above, Dr. Selck's opinions about price erosion and lost sales are contradicted by evidence from UTC. In any event, Dr. Selck acknowledges that profits from the sales of existing drugs are not UTC's only possible financing mechanism –he believes they are a "preferred method."[151] Yet he claims that:

> United's research and development efforts would be harmed by reduced revenues of Tyvaso and Tyvaso DPI in the PH-ILD market.[152]

110. What Dr. Selck fails to acknowledge is that, as of December 31, 2023, UTC had $4.9 billion in cash and marketable securities – an increase of $749 million in a year.[153] Already deducted from that

[148] UTC_PH-ILD_002310–28 at 11–12. [Lieberman, Marvin B. and David B. Montgomery, "First-Mover Advantages," *Strategic Management Journal* 9, (1988): 41–58, at 41–42].

[149] Selck Declaration, ¶98.

[150] Selck Declaration, ¶99.

[151] Selck Declaration, ¶100.

[152] Selck Declaration, ¶101.

[153] UTC 10-K, 2023, p. 61.

additional cash are UTC's recorded total R&D expenses of $408 million in 2023. This is up from $323 million in 2022. [154] As a result, UTC could give up over $500 million per year before it would have to look to outside sources of funding for its R&D program. In fact, UTC just announced a share buyback program of up to $1 billion – indicating that it believes it has more than sufficient cash to fund future R&D.[155] Furthermore, it appears that UTC can readily issue debt to fund any promising research projects as its interest expense in 2023 amounted to $59.3 million against net income of $984.8 million. [156]

111. Thus, it does not appear that UTC is in danger of having to curtail its R&D efforts due to competition from Yutrepia marketed with a PH-ILD indication.

12. REPUTATIONAL HARM

112. Dr. Selck opines that another form of indirect harm for UTC may be reputational:

> If a preliminary injunction is not granted but a subsequent permanent injunction is granted, Yutrepia may be allowed to enter the market and then be forced to withdraw. Subsequent removal of Yutrepia due to the outcome of this litigation may cause external stakeholders to view United negatively for having removed an additional product for PH-ILD patients from the marketplace.[157]

113. Dr. Selck's allusions to the fact that UTC is listed as a "public benefit corporation" do not appear to support any claim of reputational harm – other than perhaps calling into question UTC's public benefit purpose.[158]

114. Dr. Selck does not consider whether UTC has already suffered the claimed reputational harm by filing the present lawsuit that is attempting to keep "an additional product for PH-ILD patients from the marketplace." [159] This reputational harm – to the extent it exists – appears to be entirely within UTC's control.

115. Furthermore, Mr. Benkowitz appeared to be confident that UTC's reputation was solid:

> Did you say why would Liquidia become the -- I think I believe -- we believe Tyvaso will continue to be the preferred agent for very -- I mean the big one is

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[154] UTC 10-K, 2023, p. 59.

[155] Press Release, United Therapeutics Corp., United Therapeutics Corporation Announces $1 Billion Accelerated Share Repurchase Program (3/25/2024) (LIQ_PH-ILD_00000577), available at https://ir.unither.com/press-releases/2024/03-25-2024-110046740.

[156] UTC 10-K, 2023, p. F-6.

[157] Selck Declaration, ¶102.

[158] Selck Declaration, ¶103.

[159] Selck Declaration, ¶102.

> that we've got 2 years of patient data, thousands of patients on the product. The patients are -- satisfaction level is incredibly high both by the physicians and by the patients. And so they have that experience with our product, which is incredibly helpful.
>
> I think -- we think the convenience of our device as a differentiator. Ours is one (inaudible) per session. Their's 2. Ours doesn't require cleaning. Their's does. We don't have a max label dose. And so we just think, all in all, the patients and the physicians are going to prefer our product. We think the other thing that's attractive about our devices are just what's called a low-flow device and so that means that it requires less patient effort to actually breed the drug.
>
> And then as a result of that, that property or that characteristic. The drug is actually getting deeper into the lungs. So what you see with a high flow device, which is what their device is. So we think all in all, the totality of the characteristics of our device are going to be preferred by physicians and patients.
>
> **And then on the payer side, you were in these discussions right now with payers and kind of working that out. But I think we're feeling increasingly confident that there's not going to be preference, so it's going to be a level playing field. So it's really going to be up to the patient and the physician, and we feel confident about how we're going to do there.** [160]

13. IRREPARABILITY

116. Dr. Selck makes two arguments about the irreparability of any harm should an injunction not issue:

- Difficulty of quantifying the harm[161]
- Liquidia's supposed inability to pay sufficient damages[162]

117. Dr. Selck's reasoning opinion about Liquidia's supposed inability to pay sufficient damages is based on his comparison of an overstated and unsupported estimate of possible damages with Liquidia's stock market capitalization:

> To demonstrate Liquidia's likely inability to compensate United for its infringement (even if damages could be calculated), I have prepared an illustrative analysis that estimates an approximate low-end magnitude of lost revenues that United is likely to suffer if Yutrepia enters the market. … Based on this forecast, I estimate lost revenues for the Tyvaso products under conservative assumptions of 20% price erosion in the first year only and a 20% decrease in treated patients in each year. Even under these conservative

[160] LIQ_PH-ILD_00001162–71 at 1167 [Refinitiv StreetEvents, Edited Transcript, UTHR.0Q - United Therapeutics Corp at TD Cowen Health Care Conference, March 05, 2024, p. 6] (**emphasis** added).

[161] Selck Declaration, §5.2.

[162] Selck Declaration, §5.5.

> assumptions, lost revenues in a single year are approximately in the hundreds of millions of dollars. Lost revenues [redacted]. In contrast, Liquidia Corporation's market capitalization—a measure of how much the entire company is worth as determined by the stock market—was $1.139 billion as of February 12, 2024.[163]

118. I do not believe that Dr. Selck's estimate is even "illustrative" as it is contrary to UTC management's own forecasts and is based largely on an inapt analogy.[164] Dr. Selck acknowledges that his [redacted].[165] In fact, Dr. Selck states that [redacted].[166] Dr. Selck also deliberately ignored [redacted].[167] Dr. Selck's only justification for his [redacted] figures is his analysis of "hepatitis C treatments and … PCSK9 inhibitors" – which he stated were not informative in this case.[168]

119. At this point in time, I have not estimated damages. However, based on the evidence that UTC is [redacted] – much less additional price erosion or lost sales if Yutrepia launches with a PH-ILD indication – Dr. Selck's figures are significantly overstated. Furthermore, Dr. Selck has erred in a number of additional ways.

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[163] Selck Declaration, ¶147.

[164] Furthermore, his calculation is based on revenues – not profits. Dr. Selck does not start with UTC's own forecast of prices, nor does he allow any price change past the first year.

[165] Deposition of Frederic Selck, March 15, 2024 at 121:5–13; UTC_PH-ILD_009410–18 [UTHR Forecast 2023-2035 09-06-2023].

"[redacted]

[166] Deposition of Frederic Selck, March 15, 2024 at 121:14–122:2.

[redacted]

[167] Deposition of Frederic Selck, March 15, 2024 at 112:15–21.

[redacted]

[168] Selck Declaration, ¶127; Deposition of Frederic Selck, March 15, 2024 at 122:3–9. [redacted]

120. First, Dr. Selck's calculations overstate the length of the requested injunction. Dr. Selck's calculations are based on [redacted]. However, he understands that the preliminary injunction would only last just over a year -- through trial in 2025.[169] Thus his calculations of potential harm to UTC last well beyond the scope of the requested injunction.

121. Second, as discussed in Sections 7 and 8, his estimated price erosion and lost sales estimates do not distinguish between Yutrepia launching with and without a PH-ILD indication. If PH-ILD is a separate market, then you would not model price erosion in the PAH market due to competition in the PH-ILD market.

122. Third, Dr. Selck does nothing to calculate Liquidia's ability to pay beyond referring to Liquidia's stock market value. Regardless of whether Yutrepia launches with a PH-ILD indication, it will be profiting from its sales of Yutrepia with a PAH indication, yet Dr. Selck did not address this relevant source of profits.[170] Dr. Selck acknowledges that Liquidia's market capitalization may not be a perfect estimate of Liquidia's future earnings potential, but he neglected to describe how rough an estimate it is.[171] He points to Liquidia's market capitalization of $1.139 billion as of February 12, 2024 when Liquidia stock closed at $15.06.[172] However, Dr. Selck does not put that in the context that this market capitalization represented a doubling of Liquidia's stock price in two months.[173]

123. Dr. Selck's arguments about the difficulty of quantifying damages are largely directed at the "complexity of the marketplace."[174] He claims that:

> The PH-ILD market is complex and unique because it is essentially a new market.[175]

124. This statement fails for at least three reasons. First, it is not a "new" market; Tyvaso was approved for the PH-ILD indication three years ago.[176] Second, it assumes that there is a PH-ILD Market when, in

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[169] Deposition of Frederic Selck, March 15, 2024 at 152:14–17. [redacted]

[170] Deposition of Frederic Selck, March 15, 2024 at 159:2–12. [redacted]

[171] Deposition of Frederic Selck, March 15, 2024 at 146:7–11 [redacted]

[172] Selck Declaration, ¶147. Exhibit 5.2.

[173] Exhibit 5.2. LQDA closed at $7.24 on December 12, 2023.

[174] Selck Declaration, §5.2.

[175] Selck Declaration, ¶107.

[176] *See* 3/31/2021 Approval Letter

fact, there is no PH-ILD Market as discussed previously. Third, if there were a PH-ILD Market, that would make quantifying damages much easier as Dr. Selck would not have to consider competing products or companies because the but-for world would be one in which only Yutrepia and Tyvaso were competing for PH-ILD patients.

125. In my opinion, damages could be quantified in this case. Dr. Selck testified that he has never given an opinion quantifying damages in a U.S. patent litigation.[177] I have been quantifying damages from patent infringement for over 25 years and there is nothing in this case that appears to be so unique as to preclude a proper estimate of damages in the event that Liquidia is found liable for infringing the '327 Patent.

126. Comparing Liquidia's market capitalization with no forecasted evidence of either lost sales or price erosion for UTC, I conclude that Liquidia should be able to pay damages at trial in 2025 if it is found to infringe UTC's '327 Patent.

14. BALANCE OF EQUITIES

127. Dr. Selck also claims that the harm to UTC is disproportionate to the gain to Liquidia.[178] This opinion relies on what he characterizes as a back-of-the-envelope calculation to suggest that there is no viable reasonable royalty. I disagree with this claim and his back-of-the-envelope calculation because they, again, rest on a supposition that there is a PH-ILD Market and that the launch of Yutrepia will cause a massive disruption in that market.

128. Dr. Selck further claims that:

> United's investments in the Tyvaso products and in developing the PH-ILD market exceed Liquidia's investments. The harms to United if an injunction is not granted exceed the harms that Liquidia may suffer from the injunction being granted.[179]

129. These first sentence above ("United's investments") and the second sentence above ("harms to United … exceed harms [to] Liquidia") are unrelated. There is no sense in which the relative investments

[177] Deposition of Frederic Selck, March 15, 2024 at 8:17–9:12.

[redacted]

[178] Selck Declaration, §5.4.

[179] Selck Declaration, ¶149.

by UTC and Liquidia indicate any balance of equities or potential harms. Historic R&D expenditures by both companies are sunk costs and are not going to be affected by an injunction.

130. Dr. Selck then claims that:

> By relying on Tyvaso as the reference product for Yutrepia to earn approval, Liquidia is freeriding on United's efforts to bring the Tyvaso products to market without incurring the significant costs that United had to spend and risks that United had to take on the development and commercialization of the Tyvaso products.
> …
> If Yutrepia is not enjoined from entry for the PH-ILD indication, United will be harmed by losing the ability to recoup its significant research and development expenses and earn the rewards it should be able to earn from successfully taking the risk to develop the first drug in a new indication. Conversely, if Yutrepia is enjoined from entering the market for the PH-ILD indication, any lost investments into drug development that Liquidia will incur will be small compared to what United will experience; Liquidia currently does not have any clinical study results available for PH-ILD.[180]

131. As an initial matter, Dr. Selck's use of the term "freeriding" is pejorative. It is also described as one of the advantages of being second to market.[181] Dr. Selck has not identified anything, nor am I aware of anything, that Liquidia has done that could be considered illegal or unethical in choosing to get a product approved through a 505(b)(2) process.[182]

132. Dr. Selck's opinion about the balance of equities is entirely reliant on his other opinions about price erosion, lost sales and the difficulty of calculating damages. Dr. Selck's opinion is based on a simple comparison of the R&D expenditures of UTC and Liquidia. However, as I am sure Dr. Selck is aware, the entirety of UTC's R&D expenditures to obtain the PH-ILD indication are not at risk. First, UTC has already recouped at least some of those investments through its sales of Tyvaso with a PH-ILD indication since April of 2021. [redacted].[183] [redacted].[184] Second, any lost sales or price erosion due to Yutrepia launching with a PH-ILD indication would reduce UTC's profits — not eliminate them. Thus, a more accurate way to characterize UTC's risk is that it

[180] Selck Declaration, ¶154.

[181] UTC_PH-ILD_002310–28 at 11. [Lieberman, Marvin B. and David B. Montgomery, "First-Mover Advantages," *Strategic Management Journal* 9, (1988): 41–58, at 41].

[182] Selck Declaration, ¶29.

[183] Selck Declaration, ¶152; UTC 10-K, 2023, p. 56.

[184] Selck Declaration, ¶152.

might get a lower return on its investment than it otherwise would. This reduced return is equal to any lost profits damages UTC might suffer – so this discussion collapses into the prior discussions about price erosion and lost sales. To the extent that the court denies the preliminary injunction but later finds Liquidia liable for infringement of the '327 Patent, UTC would be made whole through an award of damages.

133. Dr. Selck does not address the more typical question when considering the balance of equities – the relative effects of an injunction on Liquidia compared to UTC.

134. An injunction in this case would continue to allow UTC to generate profits from the sale of Tyvaso. I do not have any opinion at the moment as to how much difference an injunction would make to UTC – *i.e.* how different UTC's profits would be with and without an injunction – and Dr. Selck does not provide this analysis either. As discussed previously, at the end of 2023 UTC had $4.9 billion in cash and marketable securities – an increase of $749 million in a year.[185] In contrast, UTC recorded total R&D expenses of $408 million in 2023 up from $323 million in 2022. [186] Furthermore, UTC reported net income for 2023 of $984.8 million (42.3% of sales) up from $727.3 million in 2022 and $475.8 million in 2021. [187] Thus, UTC is a very profitable company and its 2023 forecast evidences UTC's belief that it will continue to remain profitable even upon Liquidia's launch.

135. The harm to Liquidia from an injunction is the loss of some profits from selling Yutrepia with a PH-ILD indication. I do not have any opinion at the moment as to how much difference this would make to Liquidia – *i.e.* how different Liquidia's profits would be with and without an injunction. I do note that Liquidia's financial position is less secure than UTC's so the loss of a dollar of profits to Liquidia is going to matter more to it than the loss of a dollar of profits to UTC. In 2023 Liquidia reported revenue of $17.5 million and a net loss of $78.5 million.[188] Liquidia reported $83.7 million in the bank as of December 30, 2023, with total cash spent on operations in the 2023 of $41.6 million. [189]

136. The balance of equities in this case, from a financial perspective, rests on an opinion about the relative incremental profits and losses to UTC and Liquidia from selling Yutrepia with a PH-ILD indication. To the extent that the market is still "nascent"[190] three years after Tyvaso was approved for a

[185] UTC 10-K, 2023, p. 61.

[186] UTC 10-K, 2023, p. 59.

[187] UTC 10-K, 2023, F-6.

[188] Liquidia 10-K, 2023, p. 81.

[189] Liquidia 10-K, 2023, p. F-4, F-7.

[190] Selck Declaration, ¶107.

PH-ILD indication, it does not appear that the difference in profits will be significant. In this case, the balance of equities favors Liquidia as incremental profits will matter more to the smaller, less-profitable company.

15. SIGNATURE PAGE

137. I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Douglas G. Kidder

April 1, 2024

EXHIBIT 1

Douglas G. Kidder

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dkidder@oskr.com

CURRENT EMPLOYMENT

2008 - Present **Managing Partner** **OSKR, LLC** **Emeryville, CA**

Patent valuation and business strategy expert with over 25 years of experience analyzing patents, business opportunities and risks. Consult for clients on complex damages and licensing issues with a particular focus on technology companies. www.oskr.com

PRIOR EXPERIENCE

2014 – 2020 **Adjunct Professor** **Golden Gate University** **San Francisco, CA**

Taught a graduate-level course in the School of Accounting on damages.

2001 – 2007 **Principal** **LECG, LLC** **Emeryville, CA**

1997 – 1999 Primarily consulted for companies on damages issues arising from allegations of antitrust and intellectual property infringement.

2005 **Office Director**

Responsible for the operations of a 90-person office including reviews, hiring, firing, promotions, morale and general administration.

2001 - 2005 **Special Assistant to the Chairman, Strategy**

Advised the Chairman on corporate acquisitions and general strategic direction.

2000 - 2001 **Managing Director** **SCIENT** **San Francisco, CA**

Joined corporate strategy group to help design and implement a turn-around for this Internet consulting firm. Responsible for company organizational transition.

1999 - 2000 **VP Operations** **KENAMEA** **San Francisco, CA**

Helped develop strategy and business plan for an Internet software startup. Managed the operations of the company as we grew from 4 to 25 people.

1996 - 1997 **Principal** **MANAGEMENT RESOURCES** **Berkeley, CA**

Independent consultant performing due diligence and analyses of startup high-tech business opportunities.

1995 – 1996 **Vice President Business Development** **WALT DISNEY IMAGINEERING** **Glendale, CA**

Evaluated new business ideas for WDI including creative concepts and technology initiatives.

1993 - 1995 **Director** **VALSPAR** **Chicago, IL**

Managed the production planning, distribution and I/T functions for the $200 million Consumer Paint Division.

1992-1993 **Senior Associate** **BOOZ, ALLEN** **San Francisco, CA**
1990-1991 **Associate**
1987-1989 **Analyst**

Performed general business strategy and organization assignments across a wide range of industries. Exceptional (second in the history of the firm) promotion granted from Analyst to Associate waiving the usual requirement for an MBA.

1984 - 1986	**Lecturer**	**UC BERKELEY**	**Berkeley, CA**
	Taught an introductory computer science class.		
1986	**Chief Engineer**	**WINDWARD YACHTS**	**Oakland, CA**
	Responsible for the detailed design of custom yachts.		

OTHER BUSINESS EXPERIENCE

2013 – Present	**Naval Architect**		**Berkeley, CA**
	Design custom rowing shells for open water.		
2001 - 2013	**President**	**MAAS BOAT COMPANY**	**Richmond, CA**
	Purchased, managed and sold a company that manufactures and sells open water rowing shells in the U.S. and around the world. Primary responsibilities were design, management, marketing, finance, and license negotiation.		
2008 – 2012	**President**	**NAOWRC, Inc.**	**Richmond, CA**
	Created a national championship for open water rowing that brought together rowers from around the U.S. and the world.		
2004 – 2011	**President**	**KIDDER RACING**	**Richmond, CA**
	Developed design brief for an innovative one-person sailing skiff. Founded company and was responsible for final design, strategy, marketing and finance.		

Board Positions

Skyflow Inc. (former), NextWindow (former), Hero Arts (Advisory Board, former),Trade New Zealand (Advisory Board, former), Berkeley Rowing Club (former)

Other

Member of the Licensing Executives Society

Member of the National Associate of Business Economists

Member of The Sedona Conference

Participant in the Stanford IP Roundtable

Booz, Allen & Hamilton Professional Excellence Award

Outstanding Graduate Student Instructor Award

Significant experience evaluating new businesses.

EDUCATION

1986	M.Sc., University of California at Berkeley
1983	B.A. with Honors, Amherst College
	Elected to Sigma Xi, National Scientific Honor Society

PUBLICATIONS & PRESENTATIONS

"Are Patents Really Options?", *les Nouvelles Journal of the Licensing Executives Society*, V. 38(4), December 2003.

"Most Favored Licensee Clauses: Draining the Swamp" presentation at *Advanced Topics in IP Valuation* to the Intellectual Property Society, July 2004.

"Reasonable Royalties by the New Rules", *Dunn on Damages*, Summer 2011.

"Infringer's Profits Should Not Be the Focus of Patent Damages Cases", *Dunn on Damages*, Fall 2011.

"Simply Wrong: The 25% Rule Examined", *les Nouvelles Journal of the Licensing Executives Society*, December, 2011.

"For Want of Damages the Case was Tossed: Judge Posner's Ruling in Apple v. Motorola", *Dunn on Damages*, Fall 2012.

"Nash Bargaining and Patent Damages", *les Nouvelles Journal of the Licensing Executives Society*, March 2014.

"Lump Sums, Running Royalties and Real Options", *les Nouvelles Journal of the Licensing Executives Society*, December 2015.

Litigation Experience

Ossur Holdings Inc. and Generation II USA, Inc., v. Bellacure, Inc., Shane Sterling and Maurice Cannon. Before United States District Court, Western District of Washington at Seattle. Civil Action No: 05-CV-01552-CMP. Retained by counsel for plaintiffs, re: lost profits and unjust enrichment due to alleged theft of trade secrets in the medical device industry (osteoarthritis knee braces).

Google, Inc. v. American Blind & Wallpaper Factory, Inc. Before United States District Court, Northern District of California. Case No. C 03-5340 JF EAI. Retained by counsel for plaintiffs re: damages arising from Google's alleged infringement of American Blind & Wallpaper's trademarks.

Comcast Cable Communications Corporation, LLC v. Finisar Corporation. Before United States District Court for the Northern District of California. Case No. C 06-04206 WHA. Retained by counsel for plaintiffs re: damages arising from Comcast's alleged infringement of Finisar patent number 5,404,505.

Carter Bryant, an individual v. Mattel Inc. and Consolidated Actions. Before United States District Court for the Central District of California, Eastern Division. Case No. CV 04-9049 SGL (RNBx) Consolidated with Case No. CV 04-09059 Case No. CV OS02727. Retained by counsel for plaintiff re: damages arising from Mr. Bryant's alleged theft of copyrighted materials, breach of fiduciary duty and theft of trade secrets.

American Airlines, Inc. v. Google, Inc. Before United States District Court for the Northern District of Texas, Fort Worth Division. Case No. 4-07CV-487-A. Retained by counsel for defendant re: damages arising from Google's alleged infringement of American Airline's trademarks.

H. Richard Dallas, Shareholder Representative for dMarc v. Google Inc. Before JAMS, reference #1100054656. Retained by counsel for defendant re: damages arising from a breach of contract claim arising from Google's acquisition of dMarc.

Flashseats, LLC. v. Paciolan Inc. Before United States District Court, District of Delaware. Case No. CA 07-575 (JJF). Retained by counsel for defendant re: damages arising from Paciolan's alleged infringement of Flashseats' patent number 6,496,809.

Charlotte Russe Holding, Inc. v. Versatile Entertainment, Inc. and People's Liberation, Inc. Before Superior Court of the State of California, County of Los Angeles, Central District. Case No. BC424734. Retained by counsel for plaintiff re: damages arising from alleged breach of contract.

M&H Realty Partners V L.P. v. Aerojet-General Corporation, Boeing Realty Corporation, The Boeing Company, McDonnell Douglas Corporation. Before Superior Court for the State of California, County of Orange. Case No. 30-2008-00080378-CUTT-CXC. Retained by counsel for plaintiff re: damages arising from environmental contamination at a property redevelopment.

Firefly Digital, Inc. v. Google Inc. Before United States District Court, Western District of Louisiana, Lafayette Division. Case number 6:10cv00133-TLM-PJH. Retained by counsel for defendant re: damages arising from alleged trademark infringement.

American Technology, Inc., v. FrozenCPU.com, Inc. Before the United States District Court, Middle District of Florida, Orlando Division. Case Number 6:11-CV-110-ORLACC-GJK. Retained by counsel for defendant re: damages arising from alleged patent infringement.

C&C Jewelry Mfg., Inc. v. Trent West. Before United States District Court, Northern District of California, San Jose Division, Case No. 5:09-cv-01303-JF-HRL. Retained by counsel for plaintiff re: reasonable royalty damages arising from alleged patent infringement.

Pixart Imaging, Inc. v. Avago Technologies General IP (Singapore) PTE. LTD. Before United States District Court Northern District of California, San Jose Division. Case No. C 10-00544 JW. Retained by counsel for plaintiff re: additional royalties due from alleged breach of a patent license agreement.

EasyWeb Innovations, LLC. v. Twitter, Inc. Before United States District Court, Eastern District of New York. Case No. 2:11-cv-04550-JFB-WDW. Retained by counsel for defendant re: reasonable royalty damages arising from alleged patent infringement.

Oncology Tech, LLC v. Elekta AB and Elekta, Inc. Before United States District Court, Western District of Texas, San Antonio Division. Case No: 5:12-CV-00314-HLH. Retained by counsel for defendants re: damages arising from alleged breach of contract.

American Medical Response, Inc. v. Paramedics Plus, LLC. Before Superior Court of the State of California, County of Alameda. Case No: RG10541623. Retained by counsel for defendant re: damages arising from alleged low-cost bid for emergency medical services.

AMC Technology, L.L.C., v. Cisco Systems, Inc. Before United States District Court, Northern District of California, San Jose Division. Case No: C-11-03403 (PSG). Retained by counsel for plaintiff re: damages arising from alleged breach of contract.

Silicon Storage Technology, Inc. v. National Union Fire Insurance Company of Pittsburgh, PA and XL Specialty Insurance Company. Before United States District Court, Northern District of California. Case No: 5:13-CV-05658. Retained by counsel for defendants re: damages arising from a claim for theft of trade secrets.

Neustar, Inc. v. F5 Networks, Inc. Before United States District Court, Northern District of California, San Jose Division. Case No: CV12-02574. Retained by counsel for plaintiff re: damages arising from alleged breach of contract.

Qiang Wang v. Palo Alto Networks, Inc. Before United States District Court, Northern District of California, San Francisco Division. Case No: C 12-05579 WHA. Retained by counsel for defendant re: damages arising from alleged misappropriation of trade secrets and alleged patent infringement.

Affymetrix, Inc. v. Enzo Biochem Inc. Before United States District Court, Southern District of New York, Case No. 1:04-cv-01555-RJS. Retained by counsel for Plaintiffs re: damages arising from an alleged breach of contract.

Enzo BioChem, Inc. v. Affymetrix, Inc. Before United States District Court, Southern District of New York, Case No. 1:03-cv-08907-RJS. Retained by counsel for Defendants re: damages arising from an alleged breach of contract.

Wyde Voice, LLC and Free Conferencing Corporation v. Global IP Solutions, Inc. and Google Inc. Before Superior Court of the State of California, County of San Francisco, Case No. CGC-12-522868. Retained by counsel for defendants re: damages arising from an alleged breach of contract.

Alexander Stross v. ZipRealty, Inc. Before United States District Court, Western District of Texas, Austin Division. Civil Action No. A-13-CV-419-SS. Retained by counsel for defendants re: damages arising from alleged copyright infringement.

Collarity, Inc. v. Google, Inc. Before United States District Court, District of Delaware. Case No. 11-1103 MPT. Retained by counsel for defendants re: damages arising from alleged patent infringement.

TomTom International, B.V. v. Broadcom Corporation. Before United States District Court, Central District of California. Case No. 8:14-cv-00475 PA (DFMx). Retained by counsel for defendants re: damages arising from alleged breach of warranty.

In Re Google Inc. Privacy Policy Litigation. Before United States District Court, Northern District of California, San Jose Division. Case No. 12-CV-01382 PSG. Retained by counsel for Google re: damages arising from alleged breach of privacy policy.

Sarvint Technologies, Inc. v. Athos Works, Inc., and Mad Apparel, Inc. (and related cases filed by Sarvint against OMSignal, Ralph Lauren, Victoria's Secret, Textronics and adidas, and Sensoria). Before United States District Court, Northern District of Georgia, Atlanta Division. Civil Action No. 1:15-CV-00068-TCB. Retained by counsel for defendants re: irreparable harm arising from alleged patent infringement.

California Expanded Metal Products Co., v. ClarkWesternDietrich Building Systems LLC, James Klein and BlazeFrame Industries, Ltd. Before United States District Court, Central District of California, Case No. 2:12-cv-10791-DDP-MRWx. Retained by counsel for defendants re: damages arising from alleged breach of contract and patent infringement.

In Re: Multiple Listing Service Real Estate Photo Litigation. Before United States District Court, Southern District of California, Case No.: 14CV1158 BAS (JLB). Retained by counsel for defendant (CoreLogic) re: damages arising from an alleged breach of copyright.

TeleSign Corporation v. Twilio, Inc. Before United States District Court, Central District of California, Case No. 15-3240-PSG-SS. Retained by counsel for defendant re: irreparable harm in the context of a motion for preliminary injunction.

Quantum Corporation v. Crossroads Systems, Inc. Before United States District Court, Northern District of California, San Francisco Division, Case No. 3:14-cv-04293-WHA. Retained by counsel for plaintiff re: lost profits and reasonable royalty arising from alleged patent infringement.

United States of America ex rel. Floyd Landis v. Tailwind Sports Corp., Lance Armstrong and Johan Bruyneel. Before United States District Court, District of Columbia, Case No. 1:10-cv-00976 (CRC). Retained by counsel for Lance Armstrong re: benefits received by the U.S. Postal Service from its sponsorship of the USPS Cycling Team.

Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC, v. HyperBranch Medical Technology, Inc. Before United States District Court, District of Delaware, Case No. C.A. No. 15-1819 (LPS)(CJB). Retained by counsel for defendant re: irreparable harm in the context of a motion for preliminary injunction.

Alice Svenson, individually and on behalf of all others similarly situated, v. Google, Inc. and Google Payment Corporation. Before United States District Court, Northern District of California, Case No. CV-13-04080-BLF. Retained by counsel for defendant re: damages from alleged breach of privacy policy.

Telecom Asset Management, LLC v. Cellco Partnership d/b/a Verizon Wireless, Verizon Sourcing LLC, Verizon Corporate Resources Group LLC. Before United States District Court, Southern District of New York, Case No.: 15 Civ 2786 (SHS) (RLE). Retained on behalf of defendants re: damages from alleged breach of contract.

Celestica (USA) Inc. v. The Crossbow Group, LLC, Before JAMS, San Jose, CA. JAMS Ref. No. 1110018525. Retained by counsel for plaintiffs re: damages from alleged breach of contract.

Varentec, Inc. v. Gridco, Inc. *et al*. Before United States District Court for the District of Delaware, C.A. No. 16-217-RGA. Retained by counsel for defendants re: irreparable harm in the context of a motion for preliminary injunction.

Connectus, LLC d/b/a eDegree Advisor v. Ampush Media, Inc. and DGS Edu LLC. Before United States District Court, Middle District of Florida, Tampa Division, Case No.: 8:15-cv-02778-VMC-JSS. Retained by counsel for plaintiffs re: damages from breach of contract, unjust enrichment and unfair competition.

Doug Baird, Doug Hesse and Bob Schmitt Derivatively on Behalf of BlinkMind, Inc. v. Joe Baird, Nathan Stratton, Michael Tessler, Exario Networks, Inc., and BroadSoft, Inc. Before District Court of Harris County, Texas, 270th Judicial District, Cause No. 2015-16576. Retained by counsel for defendants Joe Baird, Nathan Stratton and BroadSoft re: damages from theft of trade secrets.

Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC, v. HyperBranch Medical Technology, Inc. Before United States District Court, District of Delaware, Case No. C.A. No. 15-1819 (LPS)(CJB). Retained by counsel for defendant re: damages from patent infringement.

Klaustech, LLC. v. AdMob, Inc. Before United States District Court, Northern District of California, Oakland Division. Case No. 10-CV-05899-JSW. Retained by counsel for defendant re: damages from patent infringement.

Google LLC, v. Anthony Scott Levandowski and Lior Ron. Before JAMS, San Francisco, Case No. 1100086069 & 1100086032. Retained by counsel for plaintiff re: damages from breach of contract, fraud, and disloyalty.

Express Mobile, Inc., v. Svanaco, Inc., BigCommerce, Inc. Before United States District Court For the Eastern District of Texas, Marshall Division. Retained by counsel for defendant re: damages from patent infringement.

Safeway, Inc. v. Sheppard Mullin Richter & Hampton, LLP. Before JAMS, San Francisco, Case No. 1220052996. Retained by counsel for defendant re: damages from legal malpractice.

Juliana Griffo v. Oculus VR, Inc. and Palmer Luckey. Before United States District Court, Central District of California, Southern Division (Santa Ana), Case No. 8:15-cv-01228-DOC (JCGx). Retained by counsel for defendants re: damages from copyright infringement.

Beijing Choice Electronic Technology Co., Ltd. v. Contec Medical Systems USA INC. and Contec Medical Systems Co., Ltd. Before United States District Court, Northern District of Illinois, Case No: 18-cv-00825. Retained by counsel for defendants re: irreparable harm in the context of a motion for a preliminary injunction and damages from patent infringement.

Alarm.com, Inc. and ICN Acquisition, LLC v. SecureNet Technologies, LLC. Before United States District Court, District of Delaware. Case No.: 1:15-cv-00807-GMS. Retained by counsel for defendants re: damages from patent infringement.

Ameranth, Inc. v. Mobo Systems (d/b/a Olo). Before United States District Court, Southern District of California, San Diego Division. Case No.: 3:12-cv-01642-JLS-NLS. Retained by counsel for defendant re: damages from patent infringement.

International Longshore and Warehouse Union and Pacific Maritime Association vs. ICTSI Oregon, Inc. Before the United States District Court for the District of Oregon. Case No. 3:12-cv-01058-SI. Retained by counsel for plaintiff and counterclaim defendant re: damages from labor slowdown.

International Code Council, Inc. v. UpCodes, Inc., Garrett Reynolds and Scott Reynolds. Before the United States District Court for the Southern District of New York. Case No. 1:17-cv-6261. Retained by counsel for defendants re: damages from copyright infringement.

United States of America v. Sushovan Tareque Hussain. Before the United States District Court, Northern District of California. Case No. CR 16-00462 CRB. Retained by counsel for defendant re: gains from fraud.

Nevro Corp., v. Stimwave Technologies, Inc. Before the United States District Court for the District of Delaware. Case No. 19-325 (CFC). Retained by counsel for defendant re: irreparable harm in the context of a motion for a preliminary injunction.

CellInfo, LLC v. American Tower Corporation and American Tower Do Brasil. Before American Arbitration Association, Boston Regional Office. Case No. 01-18-0004-5894. Retained by counsel for plaintiff re: damages from misappropriation of trade secrets and confidential information.

Booker T. Huffman v. Activision Publishing, Activision Blizzard and Major League Gaming Corp. Before the United States District Court for the Eastern District of Texas, Marshall Division. Case No. 2:19-cv-00050-RWS-RSP. Retained by counsel for defendant re: damages from copyright infringement.

PTP OneClick, LLC v. Avalara, Inc. Before the United States District Court, Western District of Washington at Seattle. Case No. 2:19-cv-00640-JLR. Retained by counsel for defendant re: damages from misappropriation of trade secrets and breach of contract.

Arendi S.A.R.L. v. Motorola Mobility LLC. Before the United States District Court, District of Delaware. Case No. 12-1601-LPS. Retained by counsel for defendant re: damages from patent infringement.

Arendi S.A.R.L. v. Google LLC. Before the United States District Court, District of Delaware. Case No. 13-919-LPS. Retained by counsel for defendant re: damages from patent infringement.

FurnitureDealer.net, Inc. v. Amazon.com, Inc., and COA, Inc. d/b/a Coaster Company of America. Before the United States District Court, District of Minnesota. Case No. 18-232 (JRT/HB). Retained by counsel for defendant re: copyright infringement.

Crown Building Maintenance, Inc. v. Metro Services Group, Jeff Dachenhaus, Mark Nolan and Derek Schulze. Before the Superior Court of the State of California, County of San Francisco. Case No. CGC-18-566118. Retained by counsel for plaintiffs re: damages from breach of contract and misappropriation of trade secrets.

Hong Kong Ucloudlink Network Technology Limited v. SIMO Holdings Inc. and Skyroam, Inc. Before the United States District Court, Northern District of California. Case No. 8-cv-05031. Retained by counsel for plaintiffs re: damages from patent infringement.

Fisher & Paykel Healthcare, Ltd v. Flexicare Incorporated. Before the United States District Court, Central District of California. Case No. 8:19-cv-00835-JVS-DFM. Retained by counsel for defendants re: damages from patent infringement.

Hughes & Company Construction, Inc. v. Weber Hung Family Trust. Before American Arbitration Association. Case No. 01-20-0004-8744. Retained by counsel for defendants / counterclaimants re: damages from breach of contract.

Equicare Health Inc. v. Varian Medical Systems, Inc. Before the American Arbitration Association. Case No.: 01-19-0002-4132. Retained by counsel for defendant re: damages from breach of contract.

Personalized Media Communications, LLC v. Netflix, Inc. Before the United States District Court, Eastern District of Texas, Marshall Division, Case No. 2:19-cv-00091-JRG. Retained by counsel for defendant re: damages from patent infringement.

Red Hydrogen, LLC v. CloudMinds (HK) Ltd. Before JAMS Arbitration, JAMS Ref. No. 1220062943. Retained by counsel for defendant re: factors relating to alter ego and damages from breach of contract.

USC IP Partnership, L.P., v. Facebook, Inc. Before the United States District Court for the Western District of Texas, Waco Division, Case No. 6:20-cv-00555-ADA. Retained by counsel for defendant re: damages from patent infringement.

Brad Peters, David Gray and Paul Staelin v. Infor (US), Inc. Before the United States District Court, Northern District of California, San Francisco Division, Civil Action No. 19-cv-8102 Retained by counsel for defendants / counter-claimant re: damages from breach of contract.

Netlist v. Samsung Electronics, Co., Ltd. Before United States District Court, Central District of California, Southern Division, Case No. 8:20-cv-993-MCS (ADSx). Retained by counsel for defendants re: damages from breach of contract.

Alexander Walker v. Kitty Hawk Corporation. Before JAMS, JAMS Ref. No. 1100110678. Retained by counsel for defendants re: damages from alleged fraud and breach of contract.

Contour Data Solutions, LLC. v. Gridforce Energy Management LLC, NAES Corporation, CDW Corporation, CDW Direct. Before United States District Court, Eastern District of Pennsylvania, Case No. 2:20-CV-03241. Retained by counsel for Gridforce and NAES re: breach of contract.

Rex Medical, L.P. v. Intuitive Surgical, Inc., Intuitive Surgical Operations, Inc. and Intuitive Surgical Holdings, LLC. Before United States District Court, District of Delaware, Civil Action No. 19-cv-5-MN. Retained by counsel for Rex Medical re: damages from patent infringement.

Estech Systems, Inc. v. Howard Midstream Energy Partners d/b/a Howard Energy Partners. Before United States District Court, Western District of Texas, Waco Division, Civil Action No.: 6-20-cv-00777. Retained by counsel for Howard Energy Partners re: damages from patent infringement.

Bay Materials, LLC v. 3M Company. Before United States District Court, District of Delaware, Civil Action No. 21-cv-1610-RGA-JLH. Retained by counsel for 3M Company re: irreparable harm in the context of a motion for a preliminary injunction.

RSB Spine, LLC v. DePuy Synthes Sales, Inc. and DePuy Synthes Products, Inc. Before United States District Court, District of Delaware, C.A. No. 19-1515-RGA. Retained by counsel for RSB Spine re: damages from patent infringement.

RSB Spine, LLC v. Medacta USA, Inc. Before United States District Court, District of Delaware, C.A. No. 18-1973-RGA. Retained by counsel for RSB Spine re: damages from patent infringement.

RSB Spine, LLC v. Precision Spine, Inc. Before United States District Court, District of Delaware, C.A. No. 18-1974-RGA. Retained by counsel for RSB Spine re: damages from patent infringement.

Quest Media & Supplies v. Aerojet Rocketdyne, Inc. Before Superior Court of the State of California, County of Sacramento, Case No. 34-2017-00207975. Retained by counsel for Quest Media re: damages from breach of contract.

Dennis P. Flynn v. Sara L. Flynn and Christopher J. Dressel. Before JAMS, Reference No. 1100111518. Retained by counsel for Dennis Flynn re: dissolution of partnerships and valuation of real estate interests.

AlphaSense v. Sentieo. Before United States District Court, District of Delaware, C.A. No. 21-1011-CFC. Retained by counsel for Sentieo re: irreparable harm in the context of a motion for preliminary injunction.

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WSOU Investments, LLC d/b/a Brazos Licensing and Development v. Canon Inc. and Canon USA, Inc. Before United States District Court, Western District of Texas, Waco Division, Case No. 6:20-cv-00981-ADA. Retained by counsel for Canon re: damages from patent infringement.

Xerox Corporation v. FujiFilm Business Innovation Corp. (f/k/a Fuji Xerox Co., Ltd.). Before International Court of Arbitration of the International Chamber of Commerce, Case No. 26311/PDP. Retained by counsel for Xerox re: damages from breach of contract.

Wahoo Fitness v. Zwift. Before United States District Court for the District of Delaware, Case No. 1-22-cv-01295-CFC. Retained by counsel for Wahoo re: irreparable harm in the context of a motion for a preliminary injunction.

National Fire Protection Association v. UpCodes. Before United States District Court for the Central District of California, Case No. 21-5262 DSF (E). Retained by counsel for UpCodes re: harm from alleged copyright infringement.

IGT v. Zynga. Before United States District Court for the Western District of Texas, Waco Division, Case No. 6:21-CV-00331-ADA. Retained by counsel for Zynga re: damages from patent infringement.

Estech Systems IP v. Public Storage. Before United States District Court for the Eastern District of Texas, Marshall Division, Civil Action No. 2:21-CV-00483. Retained by counsel for Public Storage re: damages from patent infringement.

Metricolor v. L'Oréal. Before United States District Court, Central District of California, Civil Action No. 2:16-CV-00364. Retained by counsel for L'Oréal re: damages from misappropriation of trade secrets.

ICTSI Oregon v. International Longshore and Warehouse Union (ILWU). Before United States District Court for the District of Oregon. Case No. 3:12-cv-01058-SI. Retained by counsel for defendant re: damages from labor slowdown.

Consumeron v. Maplebear Inc. d/b/a Instacart. Before United States District Court for the District of Delaware. Civil Action No. 1:21-01147-GBW-MPT. Retained by counsel for defendant re: damages from patent infringement.

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Steven G. Alves v. Herbert Feinberg; Harry Feinberg; Richard Tinervin; Gotham Enterprises and Affiliates. Before Superior Court of the State of California, County of Placer. Case No. SCV0043567. Retained by counsel for defendants re: damages from alleged breach of contract and misappropriation of trade secrets.

HID Global Corporation v. Vector Flow, Inc., Ajay Jain, Vikrant Ghai and Shailendra Sharma. Before United States District Cour for the District of Delaware. C.A. No. 21-1769 (GBW). Retained by counsel for defendants re: damages from alleged patent infringement, trade secret misappropriation, breach of contract and breach of fiduciary duty.

Insulet Corporation v. EOFlow Ltd., EOFlow, Inc., Flex Ltd., Flextronics Corporation, Flextronics Medical Sales and Marketing Ltd., Luis J. Malave, Steven DiIanni, and Ian Welsford. Before United States District Court for the District of Massachusetts. Case No. 1:23-cv-11780. Retained by counsel for defendants irreparable harm in the context of a motion for preliminary injunction.

Dairy, LLC v. Milk Moovement, Inc. Before United States District Court, Eastern District of California. Case No. 2:21-cv-02233-WBS-AC. Retained by counsel for defendants / counter-claimants re: damages from anticompetitive conduct.

Sectra Communications AB v. Absolute Software Inc. and NetMotion Software, Inc. Before United States District Court for the Western District of Washington at Seattle. Case No. 2:22-cv-0353-RSM. Retained by counsel for defendants and counterclaimants re: damages from patent infringement.

Post University v. Learneo, Inc. Before United States District Court, District of Connecticut. Case No. 3:21-cv-01242 (JBA). Retained by counsel for defendants re: damages from copyright infringement.

International Business Machines Corporation v. Zynga, Inc. Before United States District Court for the District of Delaware. Case No. 22-590-GBW. Retained by counsel for defendants re: damages from patent infringement.

EXHIBIT 2

Exhibit 2
Documents Considered

Legal Filings

First Amended Complaint, November 30, 2023
Plaintiff's Motion for Preliminary Injunction, February 26, 2024
Plaintiff's Brief in Support of its Motion for Preliminary Injunction, February 26, 2024
Plaintiff's Unopposed Motion for Leave to File Under Seal, February 26, 2024

Declarations

Declaration of Shaun R. Snader in Support of Plaintiff's Motion to Seal, February 26, 2024

Declaration of Michael J. Flynn in Support of Plaintiff's Motion for Preliminary Injunction, February 26, 2024
Declaration of Steven D. Nathan, M.D. in Support of Plaintiff's Motion for Preliminary Injunction, February 26, 2024
Preliminary Injunction Declaration of Fredric Selck, Ph.D., February 26, 2024

Depositions

Deposition of Frederick Selck, March 15, 2024
Deposition of Steven D. Nathan, March 10, 2024

Conversations

Conversation with Dr. Richard Channick, March 28, 2024.

Patents

U.S. Patent 11,826,327

Academic Literature

IHS Consulting, “The Myth of First Mover Advantage”, February 2012.
Suarez, Fernando and Gianvito Lanzolla, “The Half-Truth of First-Mover Advantage,” *Harvard Business Review*, April 2005.
Teece, David, “Profiting from technological innovation: Implications for integration, collaboration, licensing and public policy,” *Research Policy* 15, (1986): 285–305
MacKinlay, A. Craig, "Event Studies in Economics and Finance," *Journal of Economic Literature* XXXV, (1997): 13–39

Correspondence

Letter from Liqudia Technologies, Inc. to United Therapeutics Corporation Re: "Notification Pursuant to § 505(b)(3)(B) of the Federal Food, Drug, & Cosmetic Act (21 U.S.C. § 355(b)(3)(B)(i)) and 21 C.F.R. §314.52)", July 24, 2023

Public Financial Documents

Liquidia Corporation Form 10-K for the year ending December 31, 2022
Liquidia Corporation Form 10-K for the year ending December 31, 2023
Liquidia Corporation Form 10-Q for the quarter ending September 30, 2023

Refinitiv Edited Transcript UTHR.0Q - Q1 2023 United Therapeutics Corp Earnings Call, May 3, 2023
Refinitiv Edited Transcript UTHR.0Q - Q2 2023 United Therapeutics Corp Earnings Call, August 2, 2023
Refinitiv Edited Transcript UTHR.0Q - Q4 2022 United Therapeutics Corp Earnings Call, February 22, 2023

Exhibit 2

Documents Considered

Conference, March 05, 2024

United Therapeutics Corporation Form 10-K for the year ended December 31, 2022

United Therapeutics Corporation Form 10-K for the year ended December 31, 2023

Bates-Stamped Documents

UTC_PH-ILD_001008-1036
UTC_PH-ILD_001107–1120
UTC_PH-ILD_002310–2328
UTC_PH-ILD_003652–4517
UTC_PH-ILD_005113–5135
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Third Party

Thompson Reuters Eikon Stock Price Data
https://cafc.uscourts.gov/home/case-information/opinions-orders/
https://cafc.uscourts.gov/opinions-orders/22-2217.OPINION.7-24-2023_2161663.pdf
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https://pipeline.unither.com/wp-content/uploads/2021/05/2021-04-01-INCREASE-approval-FINAL-formatted.pdf
https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2022/214324Orig1s000ltr.pdf
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https://www.courtlistener.com/docket/17225404/432/united-therapeutics-corporation-v-liquidia-technologies-inc/
https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-414/subpart-K/section-414.904
https://www.justice.gov/archives/atr/operationalizing-hypothetical-monopolist-test
https://www.justice.gov/d9/2023-12/2023%20Merger%20Guidelines.pdf
https://www.liquidia.com/news-releases/news-release-details/fda-grants-tentative-approval-liquidias-yutrepiatm-treprostinil
https://www.liquidia.com/news-releases/news-release-details/liquidia-provides-update-hatch-waxman-litigation-and-host-call

Exhibit 2

Documents Considered

https://www.liquidia.com/news-releases/news-release-details/liquidia-technologies-announces-pricing-initial-public-offering
https://www.liquidia.com/products-and-pipeline/overview

https://www.prnewswire.com/news-releases/united-therapeutics-announces-fda-approval-and-launch-of-tyvaso-for-the-treatment-of-pulmonary-hypertension-associated-with-interstitial-lung-disease-301260212.html
https://www.supremecourt.gov/DocketPDF/23/23-804/298456/20240123132035555_23-____PetitionForAWritOfCertoriari.pdf

CERTIFICATE OF SERVICE

I, Nathan R. Hoeschen, hereby certify that on April 1, 2024, this document was served on the persons listed below in the manner indicated:

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